

# **Exhibit A**

Vladeck, Ph.D., Bruce C.

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<p>1 STATE OF WISCONSIN CIRCUIT COURT DANE COUNTY  2 -----X  3 STATE OF WISCONSIN, : CASE NO.  4 Plaintiff, : 04-CV-1709  5 v. :  6 AMGEN INC., et al., :  7 Defendants. :  8 -----X  9  10 IN THE COURT OF COMMON PLEAS  11 FIFTH JUDICIAL CIRCUIT  12 -----X  13 STATE OF SOUTH CAROLINA, and : STATE OF  14 HENRY D. McMASTER, in his official : SOUTH CAROLINA  15 capacity as Attorney General for : COUNTY OF  16 the State of South Carolina, : RICHLAND  17 Plaintiff, :  18 v. : CIVIL ACTION:  19 MYLAN LABORATORIES, INC. : 07-CP-40-0283  20 Defendant. :  21 -----X  22</p>	<p>1 IN THE CIRCUIT COURT OF THE CITY OF ST. LOUIS  2 STATE OF MISSOURI  3 -----X  4 STATE OF MISSOURI, ex rel., :  5 JEREMIAH W. (JAY) NIXON, :  6 Attorney General, :  7 and :  8 MISSOURI DEPARTMENT OF SOCIAL :  9 SERVICES, DIVISION OF MEDICAL : Case No.:  10 SERVICES, : 054-1216  11 Plaintiffs, : Division  12 : No. 31  13 vs. :  14 DEY INC., DEY, L.P., MERCK KGaA, :  15 EMD, INC., WARRICK :  16 PHARMACEUTICALS CORPORATION, :  17 SCHERING-PLOUGH CORPORATION, and :  18 SCHERING CORPORATION, :  19 Defendants. :  20 -----X  21  22</p>
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<p>1 IN THE COURT OF THE SECOND JUDICIAL CIRCUIT  2 IN AND FOR LEON COUNTY, FLORIDA  3 THE STATE OF FLORIDA  4 ex rel.  5 -----x  6 VEN-A-CARE OF THE FLORIDA :  7 KEYS, INC., a Florida :  8 Corporation, by and through its :  9 principal officers and directors, :  10 ZACHARY T. BENTLEY and :  11 T. MARK JONES, :  12 Plaintiffs, :  13 vs. : Civil Action  14 MYLAN LABORATORIES, INC.; MYLAN : No.: 98-3032G  15 PHARMACEUTICALS INC.; NOVOPHARM : Judge:  16 LTD., SCHEIN PHARMACEUTICAL, INC.; : William L.  17 TEVA PHARMACEUTICAL INDUSTRIES : Gary  18 LTD., TEVA PHARMACEUTICAL USA; :  19 and WATSON PHARMACEUTICALS, INC. :  20 Defendants. :  21 -----x  22</p>	<p>1 New York, New York  2 Friday, May 4, 2007  3  4  5 Videotaped Deposition of BRUCE C.  6 VLADECK, Ph.D., a witness herein, called for  7 examination by counsel for Abbott Laboratories in  8 the above-entitled matter, pursuant to Subpoena,  9 the witness being duly sworn by JOMANNA DEROSA, a  10 Notary Public in and for New York, taken at the  11 offices of Jones Day, 222 East 41st Street, New  12 York, New York, at 8:38 a.m. on Friday, May 4,  13 2007, and the proceedings being taken down by  14 Stenotype by JOMANNA DEROSA, and transcribed under  15 her direction.  16  17  18  19  20  21  22</p>

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<p style="text-align: right;">Page 142</p> <p>1 Q. And for a brand name drug, would you --      2 at the time, did you expect that there would be      3 much variation between various purchasers based      4 upon volume purchases of the brand name drug?</p> <p>5 A. I believe we had a perception that the      6 bigger the purchaser, the larger the discount      7 they were likely to be able to achieve; that the      8 very largest pharmacy chains, for instance, or      9 hospital group purchasing operations, probably      10 received the most favorable prices, but that that      11 would be -- and that some small independent      12 pharmacies might actually pay average wholesale      13 price as described in the compendia; that there      14 would be a range below that in which most of the      15 prices would actually occur.</p> <p>16 Q. Turning to generic drugs for a minute,      17 what do you understand to be the differences      18 between the market for brand name drugs and the      19 market for generic drugs?</p> <p>20 MS. BROOKER: Objection. Form.</p> <p>21 A. If we're going back to 1997 --</p> <p>22 Q. Correct.</p>	<p style="text-align: right;">Page 144</p> <p>1 get much more commoditized in a bag of salt water      2 in the drug market?</p> <p>3 A. The only quibble I would provide to      4 that question is I never really thought of it as      5 classically being part of the pharmaceutical      6 market. It was such a -- it was really a      7 hospital supply kind of market. It was such a      8 standard product that even though it was FDA      9 regulated and -- and sterility issues were so      10 forth, it tended to be -- hospitals tend to stock      11 it, for example, in sterile supplies, put it on      12 their cost report as part of sterile supplies      13 rather than through their pharmacies.</p> <p>14 Q. But a home infusion provider reimbursed      15 under Part B, for example, might be reimbursed      16 for sodium saline solution.</p> <p>17 Was that your understanding in '97?</p> <p>18 MS. BROOKER: Objection. Form.</p> <p>19 A. Yes, but whether that was as a supply      20 or a drug, I honestly couldn't tell you. I would      21 have thought of it as a supply.</p> <p>22 Q. Turning to the market of it, whether we</p>
<p style="text-align: right;">Page 143</p> <p>1 A. -- I think it's fair to say that I had      2 really only a very limited understanding of the      3 marketplace for generic drugs and an even more      4 limited understanding of the difference between      5 the market for generic drugs and for brand drugs.</p> <p>6 And, again, my perception at the time      7 was that that was likely more like a commodity      8 market in which there was probably more      9 purchasing power on the part of the large      10 purchasers, but not the same ability to raise      11 prices on the up-side to small purchasers that      12 prevailed on the brand name side.</p> <p>13 Q. I'd like to focus you just for a      14 minute, before we turn to a specific document,      15 about a particular generic drug. I think you      16 mentioned commodities. Are you familiar with      17 sodium saline solution?</p> <p>18 A. Yes.</p> <p>19 Q. It's a bag of salt water, essentially.</p> <p>20 Correct?</p> <p>21 A. That's correct.</p> <p>22 Q. Would you agree with me that you can't</p>	<p style="text-align: right;">Page 145</p> <p>1 call it a drug or -- or a supply, did you have an      2 understanding, in 1997, of what the market would      3 look like for a product such as sodium saline      4 solution?</p> <p>5 MS. BROOKER: Objection. Form.</p> <p>6 MR. BREEN: Objection. Form.</p> <p>7 A. Yes, I did.</p> <p>8 Q. And what was your understanding?</p> <p>9 A. Well, I actually -- in the 1980s, I      10 believe, when I was first becoming involved in      11 some of these issues in health care economics was      12 the first development of hospital group      13 purchasing operations, and I recall -- and the      14 first widespread circulation of the -- of "Modern      15 Healthcare," the magazine, and I recall monthly      16 headlines in "Modern Healthcare" about group      17 purchasing operations being -- achieving      18 discounts of 98 and 99 percent in their purchase      19 of basic infusion products and sterile supplies.</p> <p>20 So, my perception was that on the      21 supply market, which, again, I understood and      22 still would contend is actually a separate market</p>

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<p>1 from the pharmaceutical market that list prices,      2 are essentially entirely meaningless and that      3 only the weakest and smallest scale buyers pay      4 anything close to it.</p> <p>5 Q. And so, as of 1993, for example, would      6 you be surprised if a single bag of sodium saline      7 solution sold to a provider who bought maybe five      8 would pay \$10 per bag, and a large purchaser who      9 bought a very large volume would pay less than a      10 dollar?</p> <p>11 MS. BROOKER: Objection. Form.</p> <p>12 A. I would not have been surprised.</p> <p>13 Q. Okay. So, to that extent that --      14 President Clinton referring to a 10-to-1 ratio is      15 something that would be consistent with your      16 understanding of that particular market.      17 Correct?</p> <p>18 MS. BROOKER: Objection. Form.</p> <p>19 Q. I'm sorry. You have to verbalize.</p> <p>20 A. Again, I would have thought that market      21 was a subset of the supplies market rather than      22 the drug market.</p>	<p>1 A. That would be a question I never      2 thought about before today. But today I would      3 say that we always made the distinction between -      4 - between drugs and -- and supplies. And, again,      5 I would fall back on the Medicare green eyeshade      6 distinction between what's sterile supplies and      7 what's pharmacy.</p> <p>8 MR. COOK: Let's take a break.</p> <p>9 THE VIDEOGRAPHER: The time is 11:28      10 a.m. We're going off the record, concluding Tape      11 No. 2 in the deposition of Dr. Bruce Vladeck in      12 the matter of In re Pharmaceutical Average      13 Wholesale Price Litigation.</p> <p>14 (Recess taken.)</p> <p>15 THE VIDEOGRAPHER: The time is 11:46      16 a.m. We're going back on the record, starting      17 Tape No. 3 of the deposition of Dr. Bruce Vladeck      18 in the matter of In re Pharmaceutical Average      19 Wholesale Price Litigation.</p> <p>20 Q. Doctor, based upon what we were talking      21 about just before the break, would it be fair to      22 say that while you were administrator of HCFA,</p>
<p>1 Q. That was my question. But you would      2 have distinguished between the drug market, where      3 10-to-1 would not -- you would not expect to see.      4 Correct?</p> <p>5 A. That's correct.</p> <p>6 Q. And the supply market, where sodium      7 saline solution would be found, where there could      8 be a huge variation between a small purchaser      9 purchasing at list price and a very large      10 purchaser purchasing at 99 percent off of list      11 price?</p> <p>12 MS. BROOKER: Objection. Form.</p> <p>13 A. I would have made such a distinction,      14 and I would not have been surprised to see those      15 sorts of differentials of the supply market.</p> <p>16 Q. And in between the commodities supply      17 market of sodium saline and the patent-protected      18 market of a brand name drug, would you expect      19 generic drugs to be somewhere between those two      20 extremes?</p> <p>21 MS. BROOKER: Objection. Form.</p> <p>22 MR. BREEN: Objection. Form.</p>	<p>1 you did not understand published average      2 wholesale price to be the average of prices at      3 which wholesalers were selling their drugs to      4 their customers?</p> <p>5 A. It would -- it would be fair to say      6 that I did not believe it was, in fact, an      7 empirical estimate, that rather it was a -- an      8 amount reported by the manufacturer to -- of the      9 compendium compilers or whatever, yes.</p> <p>10 Q. And, again, akin to a sticker price?</p> <p>11 A. That's correct.</p> <p>12 Q. Where did you get that understanding?</p> <p>13 A. I believe that was probably what my      14 staff explained to me when I first encountered      15 the concept sometime after I took office.</p> <p>16 Q. Do you recall anybody within HCFA who      17 was under the belief that average wholesale price      18 was an average of prices at which wholesalers      19 sold drugs to customers?</p> <p>20 MS. BROOKER: Object to form. And I      21 would just instruct the witness, just, you know,      22 be mindful of not disclosing deliberations,</p>
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<p>1 facts from OIG in the form of an OIG report?</p> <p>2 MS. BROOKER: Objection. Form.</p> <p>3 A. You'll have to ask -- I don't know</p> <p>4 quite how to answer that question. I don't know</p> <p>5 if you want to rephrase it, but --</p> <p>6 Q. I'm happy to. It -- it was -- it was a</p> <p>7 bad question. I can break it up into little --</p> <p>8 little bites.</p> <p>9 HCFA would receive facts from OIG,</p> <p>10 correct, in the form of these reports?</p> <p>11 MS. BROOKER: Objection. Form.</p> <p>12 A. Yes.</p> <p>13 Q. As the administrator of HCFA, you had</p> <p>14 an expectation that your employees would consider</p> <p>15 facts presented to the agency for what they were;</p> <p>16 whether true or -- or false. Correct?</p> <p>17 MS. BROOKER: Objection. Form.</p> <p>18 A. Yes, absolutely.</p> <p>19 Q. Okay. Did you rely upon the OIG, in</p> <p>20 its reports, to represent accurate facts to your</p> <p>21 agency?</p> <p>22 A. We -- we had a moderate degree of</p>	<p>1 part of your earlier question of this one because</p> <p>2 the Inspector General demonstrated a pretty</p> <p>3 consistent proclivity to document instances in</p> <p>4 which policy was producing untoward results or</p> <p>5 excess expenditures or so forth, even though we</p> <p>6 believed, and they were aware that we had no</p> <p>7 discretion to make any changes in them.</p> <p>8 Q. Okay. So, to the extent that you were</p> <p>9 able to make policy changes, did you expect your</p> <p>10 staff to take into consideration those facts in</p> <p>11 formulating policy changes?</p> <p>12 A. Absolutely. Yes, sir.</p> <p>13 Q. And to the extent the policy changes</p> <p>14 required legislation from Congress, did you</p> <p>15 expect your staff to take these facts and factor</p> <p>16 them into recommendations to Congress for policy</p> <p>17 changes and legislation?</p> <p>18 A. Yes.</p> <p>19 Q. In that context, I'd like to look at</p> <p>20 the particular purported facts at least that are</p> <p>21 reported in Appendix 2 of Exhibit Abbott 082.</p> <p>22 You'll see it's a -- it's a table with a fairly</p>
<p>1 confidence in the reliability of the information</p> <p>2 they presented.</p> <p>3 Q. So, sometimes the information would be</p> <p>4 inaccurate. Correct?</p> <p>5 A. That's correct.</p> <p>6 Q. And you expected your staff to at least</p> <p>7 attempt to distinguish between the good data and</p> <p>8 the bad data that came from OIG in these reports.</p> <p>9 Correct?</p> <p>10 MS. BROOKER: Objection. Form.</p> <p>11 A. I -- I think it would be more -- more</p> <p>12 usual to object by -- to the methodology by which</p> <p>13 the facts were presented or the facts were</p> <p>14 obtained or presented than arguing about a</p> <p>15 specific number or something of that sort.</p> <p>16 Q. To the extent that the facts appeared</p> <p>17 to be reliable as they were presented to HCFA,</p> <p>18 did you have an expectation of whether or not</p> <p>19 your staff would consider those facts in</p> <p>20 developing policy within the administration?</p> <p>21 MS. BROOKER: Objection. Form.</p> <p>22 A. Well, that's -- that's the complicated</p>	<p>1 large number of numbers on it.</p> <p>2 Now, it says:</p> <p>3 "Invoice Price For Selected Drugs At</p> <p>4 the Dialysis Facilities Reviewed."</p> <p>5 And in the left-hand column, can you</p> <p>6 see it has three drugs, Calcigex, Inferon, and</p> <p>7 vancomycin?</p> <p>8 A. Yes.</p> <p>9 Q. Do you know what Calcigex, Inferon, and</p> <p>10 vancomycin are?</p> <p>11 A. I know what vancomycin is. I'm not</p> <p>12 familiar with the other two.</p> <p>13 Q. Okay. Tell me, what is vancomycin?</p> <p>14 A. Vancomycin is a fourth generation</p> <p>15 broad-spectrum antibiotic.</p> <p>16 Q. And in 1992 it was a multiple-source</p> <p>17 product. Correct?</p> <p>18 A. I don't know.</p> <p>19 Q. If you can see on this chart, at least</p> <p>20 OIG purports to represent, under each of Calcigex</p> <p>21 and Inferon, the "S" in parentheses, and then</p> <p>22 with vancomycin there's an "M" in parentheses.</p>
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<p>1 And in the footnotes, the "S" indicates,      2 according to the OIG, that Calcigex and Inferon      3 are single-source drugs, and that the vancomycin      4 is a multiple-source drug.      5 Do you see that?      6 A. Yes, I do.      7 Q. Okay. Leaving aside knowing exactly      8 when vancomycin went generic -- well, let me stop      9 for a minute.      10 Is it your understanding that today      11 vancomycin is generic?      12 A. Yes.      13 Q. Okay. And it's just a question -- you      14 don't know when it went generic and when it went      15 off patent. Correct?      16 A. That's correct.      17 Q. Okay. The array to the right of each      18 of these drugs purports to be per-unit cost.      19 Correct?      20 A. That's my understanding of the table,      21 yes.      22 Q. And it lays out a number of numbers.</p>	<p>1 drugs at issue in -- in this case. Correct?      2 A. Yes.      3 Q. And did you have an understanding of      4 that before meeting with the Department of      5 Justice or did you only obtain that when you      6 first -- when you first started preparing for      7 this deposition?      8 A. I only became aware --      9 MS. BROOKER: I would just instruct you      10 to be mindful not to disclose any conversations      11 you've had with counsel in this case. You can      12 state what your understanding is.      13 A. I -- I became aware that vancomycin was      14 involved in this case within the last few weeks.      15 Q. Thank you. Do you see that the AWP for      16 vancomycin is reported by the OIG to be \$19.17?      17 A. Yes.      18 Q. And the EAC has reported it to be \$.5.      19 Correct?      20 A. That's what they reported, yes.      21 MR. BREEN: Objection. Form.      22 Q. So, that would appear to be a -- a</p>
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<p>1 To the right-hand side there are two other      2 columns or three other columns, but two in      3 particular labeled "EAC" and "AWP."      4 Do you see that?      5 A. I do.      6 Q. EAC, at the bottom, is defined as:      7 "The estimated acquisition cost      8 calculated using the median invoice price,      9 according to OIG."      10 Right?      11 A. Right.      12 Q. And AWP is defined as:      13 "The average wholesale price being the      14 median Red Book price for the generic form of the      15 drug, or to the extent there's not a generic      16 form, presumably the AWP for the only form of the      17 drug."      18 Do you see that?      19 A. Yes.      20 Q. I'd like to focus first just on      21 vancomycin.      22 You understand vancomycin is one of the</p>	<p>1 ratio of about four -- just under 4-to-1 between      2 what the OIG is reporting as the estimated      3 acquisition cost and the AWP for vancomycin in      4 1992?      5 A. That's --      6 MS. BROOKER: Objection. Form.      7 A. -- that's what it shows, yes.      8 Q. And -- and, again, I realize that this      9 is not a report that -- that you -- that -- that      10 you saw or you prepared, but just to round out      11 laying out the facts as they're relevant now and      12 -- and later in the deposition, if you'll look      13 for me at the array of prices for vancomycin in      14 1992, according to the OIG, you'll see that -- am      15 I correct that the lowest invoice price      16 discovered by the OIG in this report for      17 vancomycin was \$3.45? Correct?      18 A. That appears to be the case, yes.      19 Q. And the highest that the OIG reported      20 to HCFA in 1992 was \$26.61.      21 Correct?      22 MS. BROOKER: Objection. Form.</p>

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<p>1       A. That's correct.</p> <p>2       Q. We were talking a little bit earlier</p> <p>3       about the -- the range of prices that a -- a</p> <p>4       commodity, a supply such as sodium chloride</p> <p>5       solution might have, being as much as 100-to-1.</p> <p>6       Correct? You recall that?</p> <p>7       A. Yes.</p> <p>8       Q. Okay. As to generic drugs, would it be</p> <p>9       consistent with your understanding, between 1993</p> <p>10      and 1997, that a generic drug such as vancomycin</p> <p>11      could have a market range of prices as wide as</p> <p>12      that reflected in this chart?</p> <p>13      MS. BROOKER: Objection. Form.</p> <p>14      A. I am -- I think the most accurate way</p> <p>15      to answer that was I am surprised, as of today,</p> <p>16      to see that kind of data, and I think I would</p> <p>17      have been even more surprised, during the '93 to</p> <p>18      '97 period, to see that kind of data.</p> <p>19      Q. But this is data that was reported to</p> <p>20      your agency. Correct?</p> <p>21      A. That's -- that's my understanding, yes.</p> <p>22      Q. And you would have expected members of</p>	<p>1       vancomycin, would you expect your staff to take</p> <p>2       into account the difference between single-source</p> <p>3       drug prices and multiple-source drug prices in --</p> <p>4       in considering changes to Medicare payment</p> <p>5       policies?</p> <p>6       MS. BROOKER: Objection. Form.</p> <p>7       A. The only thing I can observe</p> <p>8       empirically is that I don't recall, in our</p> <p>9       conversations over the years about changing</p> <p>10      Medicare drug pricing policy, the distinction</p> <p>11      between brand and generics arising very often, if</p> <p>12      at all.</p> <p>13      Q. At the time this report was -- was</p> <p>14      written, am I correct that Medicare was</p> <p>15      reimbursing at undiscounted AWP for Part B drugs?</p> <p>16      Correct?</p> <p>17      MS. BROOKER: Objection. Form.</p> <p>18      A. I -- I believe that's correct.</p> <p>19      Q. It was either EAC, according to survey</p> <p>20      --</p> <p>21      A. Right.</p> <p>22      Q. -- or AWP. Right?</p>
<p style="text-align: center;">Page 175</p> <p>1       your staff to have taken this data into account</p> <p>2       in either a -- and let's start with establishing</p> <p>3       Medicaid or Medicare reimbursement policy.</p> <p>4       MS. BROOKER: Objection. Form.</p> <p>5       A. I would have expected, given the nature</p> <p>6       of this report then, to have been much more</p> <p>7       influenced by the bolded section in the box on</p> <p>8       Page 2.</p> <p>9       Q. And what aspect of that would you</p> <p>10      expect them to be influenced by?</p> <p>11      A. Again, the finding that -- that most</p> <p>12      prices were, in fact, below the AWP, but that in</p> <p>13      two of the cases the differential was 15 to 20</p> <p>14      percent.</p> <p>15      Q. And that would refer, presumably, going</p> <p>16      back to Appendix 2, to the Calcigex and Inferon?</p> <p>17      A. I -- presumably, yes.</p> <p>18      Q. Because those were the single-source</p> <p>19      drugs. Correct?</p> <p>20      A. Yes.</p> <p>21      Q. And to the extent that Medicare</p> <p>22      reimbursed for the multiple-source drug here,</p>	<p style="text-align: center;">Page 177</p> <p>1       A. The only reason I hesitate in response</p> <p>2       to your question is trying to remember whether</p> <p>3       dialysis drugs were treated separately from other</p> <p>4       Part B drugs, but I don't believe they were.</p> <p>5       Q. To the extent that -- that dialysis</p> <p>6       drugs were reimbursed pursuant to 405.517, they</p> <p>7       were being reimbursed by Medicare at 100 percent</p> <p>8       of AWP. Correct?</p> <p>9       A. That is correct.</p> <p>10      Q. And to the extent that the data on the</p> <p>11      chart at Appendix 2 is -- is accurate, that would</p> <p>12      indicate that for Calcigex, for example, if it</p> <p>13      were reimbursed under that methodology, am I</p> <p>14      correct that every single one of the providers</p> <p>15      surveyed would be reimbursed at an amount in</p> <p>16      excess of their acquisition cost? Correct?</p> <p>17      A. That is correct.</p> <p>18      Q. And for Inferon, all but two of the</p> <p>19      providers would have been reimbursed at above</p> <p>20      their acquisition cost. Correct?</p> <p>21      MS. BROOKER: Objection. Form.</p> <p>22      A. That's what it shows, yes.</p>

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<p>1 Q. And for vancomycin, at least one      2 provider would have had a cost of \$3.45 and a      3 reimbursement amount of \$19.17. Correct?      4 A. That's what the charge shows, yes.      5 Q. I'm getting a little bit ahead of      6 myself, but did you ever have discussions within      7 HCFA about whether to change that reimbursement      8 methodology for drugs such as this?</p> <p>9 MS. BROOKER: I'm going to instruct you      10 to be mindful of not discussing internal pre-      11 decisional deliberations on the record.</p> <p>12 A. We proposed, a number of times, to      13 change the methodology, and, in fact, the      14 proposal cited by the President, in his speech      15 that we discussed earlier, was one that we had      16 been advocating for -- within the administration      17 since, I believe, about 1995.</p> <p>18 I think it is fair to say as well that      19 I believed, as -- as far back as '95, that 85      20 percent of average wholesale price as a payment      21 method was inferior to something closer than      22 average acquisition cost, but that the</p>	<p>1 that the Office of Management and Budget, and      2 perhaps the Department of Health and Human      3 Services themselves, would not authorize us to      4 undertake the data collection to determine      5 acquisition costs, and that we -- our perception      6 was we did not believe we had the authority to go      7 to a percentage of AWP as an alternative      8 methodology without legislation.</p> <p>9 Q. Well, the -- the regulation that was      10 promulgated in 1991 providing for estimated      11 acquisition cost according to a survey or average      12 wholesale price as published in the Red Book, was      13 promulgated by the Department of Health and Human      14 Services. Correct?</p> <p>15 A. That is correct.</p> <p>16 Q. And an alternative regulation changing      17 that rule also could have been promulgated by the      18 Department of Health and Human Services any time      19 prior to the enactment of the Balanced Budget Act      20 of 1997. Correct?</p> <p>21 MS. BROOKER: Objection. Form.</p> <p>22 A. I -- I'd have to check, but it was my</p>
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<p>1 administrative difficulties, and the potential      2 administrative burden on physicians as a      3 political issue, if not a real issue, made it      4 likelier that we would be able to succeed with      5 the legislative proposal still tied to AWP than      6 one that went all the way back to its acquisition      7 costs.</p> <p>8 Q. Now, as I understand it, from '91 --      9 strike that.</p> <p>10 As I understand it, during the time you      11 were a HCFA administrator, from 1993 until 1997,      12 reimbursement for Part B drugs under Medicare,      13 under the regulation 405.517, was made pursuant      14 to HHS regulation. Correct?</p> <p>15 A. That is correct.</p> <p>16 Q. And that could have been changed      17 without legislation. Correct?</p> <p>18 MS. BROOKER: Objection. Form.</p> <p>19 A. Theoretically, yes. We were -- it was      20 my perception, during that period, that the      21 statute -- the statute offered us the alternative      22 of an acquisition price-based methodology, but</p>	<p>1 perception at the time that our legal authority      2 pretty much left us with those -- in the absence      3 of further legislation, pretty much left us with      4 those two alternatives; in other words, 100      5 percent of AWP or actual acquisition price.</p> <p>6 My -- I don't recall whether that was      7 because of a perception that Congress would      8 object to any effort to use a fraction of AWP or      9 -- I don't -- the opinion that we had only those      10 two alternative -- let me restate that.</p> <p>11 It was my belief, at the time, that the      12 -- having only those two alternatives was an      13 unavoidable reality. Whether that was legal or      14 political, I'm not sure I was clear at the time,      15 and I'm certainly not clear now.</p> <p>16 Q. So, as I understand it, between 1993      17 and 1997, according to regulation, HCFA could      18 reimburse based upon two methodologies.</p> <p>19 Correct?</p> <p>20 A. That's correct.</p> <p>21 Q. One was the published average wholesale      22 price. Correct?</p>

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New York, NY

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1    Correct?	1    A. That's vancomycin.
2       A. That's correct.	2    Q. And that's the same drug as we talked
3    Q. Do you have a memory of reviewing this	3    about earlier with respect to the 1992 report on
4    report in 1997?	4    dialysis related drugs?
5    A. No.	5    A. Yes.
6    Q. If you look at the page Roman Numeral	6    Q. And the same drug that's involved, in
7    II of the executive summary, the first sentence	7    part at least, in this lawsuit against Abbott?
8    of the -- at the top of the page with the first	8    A. So I understand.
9    paragraph? Do you see it indicates that Medicare	9    Q. If you turn back to Page B-3.
10   allowed between two and ten times the actual	10   This chart shows various points,
11   average wholesale prices offered by drug	11   according to OIG, across the top, the fourth of
12   wholesalers and group purchasing organizations	12   which is the lowest wholesale price found,
13   for eight of the 22 drugs that were reviewed?	13   according to the OIG, for this drug.
14   A. That's what it says, yes.	14   Could you tell me, what is the lowest
15   Q. That would be consistent, wouldn't it	15   wholesale price found that the OIG reported for
16   be, with President Clinton's radio address	16   vancomycin in 1996 in this report?
17   shortly after the issuance of this report about	17   A. \$3.45.
18   prices being -- AWP being up to ten times up to	18   Q. If you recall, that's the same price
19   acquisition costs. Correct?	19   that OIG reported as the lowest invoiced price
20   MS. BROOKER: Objection to form.	20   for vancomycin in its 1992 report on dialysis
21   A. I guess it would be.	21   related drugs; wasn't it?
22   Q. If you can turn to Page B-3. It's	22   MS. BROOKER: Objection. Form.
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1   Appendix B of the report and the last page of the	1   A. I'm sorry. Could you repeat the
2   Appendix B. It's a chart entitled "Summary of	2   question?
3   wholesale prices and estimated savings for 1996"?	3   Q. Sure. You and I looked earlier at a
4   A. I see that, yes.	4   1992 report on dialysis related drugs?
5   Q. The very last drug discussed here is J	5   A. That's correct.
6   3370, along the bottom left-hand corner there?	6   Q. And it showed a number of invoice
7   A. Yes. I see that.	7   prices for vancomycin in an array?
8   Q. And that's HCPCS code. What's a HCPCS	8   A. Right.
9   code, Dr. Vladeck?	9   Q. And the highest price was just over
10   A. It's the system by which HCFA assigned	10   \$26, you'll recall?
11   unique billing numbers for most of the services	11   A. That's correct.
12   that were billable under Medicare. Unfortunately,	12   Q. And the lowest invoice price that OIG
13   there wasn't already a standard industry	13   found for vancomycin in 1992 was \$3.45.
14   nomenclature somewhere.	14   Correct?
15   Q. If you turn the page to Page C-2? It's	15   MS. BROOKER: Objection to form.
16   another chart with HCPCS codes in the left-hand	16   A. That's correct.
17   column and "drug description" immediately to the	17   Q. And so in 1997 OIG is reporting to HCFA
18   right?	18   again that the lowest price available for
19   A. Yes, sir.	19   vancomycin, according to their review, was \$3.45?
20   Q. Do you see what at least this OIG	20   MS. BROOKER: Objection to form.
21   report attributes to be the drug associated with	21   A. Yes, sir.
22   Code J 3370?	22   Q. If you turn to Nancy-Ann Min DeParle's

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<p>1 October 1, 1997, response memo, as with the  2 earlier agency response that went out over your  3 name that we reviewed for the -- for the report  4 on generic drugs reimbursable by Medicaid, the  5 first line indicates:</p> <p>6 "We reviewed the above-referenced  7 report."</p> <p>8 Would you expect staff within HCFA to  9 have reviewed this particular report as indicated  10 in this memo?</p> <p>11 A. I'm sorry. I think I need about a  12 five-minute break to regain my concentration.</p> <p>13 THE VIDEOGRAPHER: The time is 2:29  14 p.m. We're going off the record with Tape No. 4.  15 (Recess taken.)</p> <p>16 THE VIDEOGRAPHER: The time is 2:43  17 p.m. We're going back on the record, continuing  18 with Tape No. 4.</p> <p>19 Q. Dr. Vladeck, I'd like to move to a  20 completely different subject. We had talked  21 earlier about whether AWP represented acquisition  22 costs for manufacturers. You were aware, were</p>	<p>1 prices that would be represented by, for example,  2 contract sales with individual customers?</p> <p>3 A. That was my understanding, yes.</p> <p>4 Q. And that there were various discount  5 structures and rebates and chargebacks that went  6 into whatever the final price would be to a  7 particular customer.</p> <p>8 MS. BROOKER: Objection. Form.</p> <p>9 MR. AZORSKY: Objection.</p> <p>10 A. I don't know that I was sophisticated  11 enough at the time to know about rebates and  12 chargebacks, but certainly in the sense that  13 there were discounts of differential amounts from  14 those published prices I was aware of.</p> <p>15 Q. At any time did HCFA communicate with  16 manufacturers about what HCFA expected the  17 published prices to reflect?</p> <p>18 MS. BROOKER: Objection. Form.</p> <p>19 A. I do not recall any specific  20 instructions of which I was aware. I don't  21 recall any such.</p> <p>22 Q. I'd like to contrast that, please, with</p>
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<p>1 you not, when you were administrator of HCFA,  2 that manufacturers were publishing prices.  3 Right?</p> <p>4 MS. BROOKER: Objection. Form.</p> <p>5 A. You'll have to elaborate on your  6 question a little bit more.</p> <p>7 Q. Sure. We had talked before about  8 published prices that manufacturers would publish  9 to the world as a list price, for example?</p> <p>10 A. That's correct.</p> <p>11 Q. And you're aware that manufacturers  12 would have, on the one hand, a published price?</p> <p>13 Correct?</p> <p>14 MS. BROOKER: Objection. Form.</p> <p>15 A. When you say "on the one hand," that  16 implies there's another hand.</p> <p>17 Q. There will be another hand.</p> <p>18 A. Yes. Right.</p> <p>19 My understanding at the time was that  20 manufacturers would have a published price which  21 would be taken as the average wholesale price.</p> <p>22 Q. And but there would be various market</p>	<p>1 the Medicaid rebate program. Are you familiar  2 with the Medicaid rebate program?</p> <p>3 A. In general terms, yes.</p> <p>4 Q. Okay. Could you give me your general  5 understanding of what the Medicaid rebate program  6 is?</p> <p>7 A. My understanding of the Medicaid rebate  8 program was that in -- manufacturers had the  9 opportunity to enter into agreements with state  10 Medicaid programs in which the state programs  11 would forego from the creation of a formulary or  12 an approved drug list in exchange for which they  13 would provide the program with a rebate relative  14 to the price that Medicaid was paying for the  15 ingredient cost of the drugs.</p> <p>16 Q. And so under the Medicaid rebate  17 program if I'm a drug manufacturer and I want my  18 drug to be reimbursed under a particular state's  19 Medicaid program, I would have to enter into an  20 agreement with the state. Correct?</p> <p>21 A. That's correct.</p> <p>22 Q. And the agreement would provide that I</p>

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<p style="text-align: right;">Page 10</p> <p>1 Videotaped Deposition of THOMAS A.      2 SCULLY, a witness herein, called for examination by      3 counsel for Abbott Laboratories in the above-entitled      4 matter, pursuant to subpoena, the witness being duly      5 sworn by SUSAN L. CIMINELLI, a Notary Public in and      6 for the District of Columbia, taken at the offices of      7 Jones Day, 51 Louisiana Avenue, Northwest,      8 Washington, D.C., at 8:49 a.m. on Tuesday, May 15,      9 2007, and the proceedings being taken down by      10 Stenotype by SUSAN L. CIMINELLI, CRR, RPR, and      11 transcribed under her direction.      12      13      14      15      16      17      18      19      20      21      22</p>	<p style="text-align: right;">Page 12</p> <p>1 APPEARANCES (continued):      2      3 On behalf of the U.S. Department of      4 Health and Human Services:      5 TROY A. BARSKY, ESQ.      6 U.S. Department of Health and Human Services      7 CMS Division      8 C2-05-23      9 7500 Security Boulevard      10 Baltimore, MD 21244-1850      11 (410) 786-8873      12 troy.barsky@hhs.gov      13      14 On behalf of the State of California:      15 NICHOLAS N. PAUL, ESQ.      16 Supervising Deputy Attorney General      17 Civil Prosecutions Unit      18 P.O. Box 85266      19 110 West A Street, #1100      20 San Diego, CA 82186      21 (619) 688-6099      22 nicholas.paul@doj.ca.gov</p>
<p style="text-align: right;">Page 11</p> <p>1 APPEARANCES:      2      3 On behalf of the United States of America:      4 GEJAA T. GOBENA, ESQ.      5 JOHN K. NEAL, ESQ.      6 ANDREW MAO, ESQ.      7 U.S. Department of Justice      8 Civil Division      9 601 D Street, Northwest      10 PHB - 9028/P.O. Box 261      11 Washington, D.C. 20044      12 Gejaa.Gobena@usdoj.gov      13 (202) 307-1088      14      15      16      17      18      19      20      21      22</p>	<p style="text-align: right;">Page 13</p> <p>1 APPEARANCES (continued):      2      3 On behalf of the State of Alabama:      4 ROGER BATES, ESQ.      5 Hand Arendall, L.L.C.      6 1200 Park Place Tower      7 2001 Park Place North      8 Birmingham, AL 35203      9 (205) 502-0105      10 Rbates@handarendall.com      11      12 On behalf of the State of Florida:      13 MARY S. MILLER, ESQ.      14 Office of the Attorney General of Florida      15 PL-01, The Capitol      16 Tallahassee, FL 32399-1050      17 (850) 414-3600      18 Mary_Miller@oag.state.fl.us      19      20      21      22</p>

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<p>1 Q. Pardon me?</p> <p>2 A. I'll give you an example of how that</p> <p>3 works. If you got Calcijex or Zemplar, that's a</p> <p>4 fairly complicated fighter of vitamin D</p> <p>5 reimbursement. And what the AWPs were and what the</p> <p>6 relevant AWPs were in that context when I was at CMS.</p> <p>7 So carriers had the discretion, for</p> <p>8 example, in that case to pay Calcijex and Zemplar the</p> <p>9 same thing and they were different drugs. They</p> <p>10 calculate AWP based on different things. So the</p> <p>11 carriers have a lot of discretion when CMS doesn't</p> <p>12 give them a national coverage decision what to cover</p> <p>13 and in many cases what to pay.</p> <p>14 Q. At the -- at the bottom of the page of the</p> <p>15 first page, it says that "on May 1st, 2000, First</p> <p>16 Data Bank provided these new average wholesale prices</p> <p>17 to state Medicaid programs." Do you see that?</p> <p>18 A. Yes.</p> <p>19 Q. And is it your understanding that the,</p> <p>20 these DOJAWPs were made available to state Medicaid</p> <p>21 programs?</p> <p>22 MR. GOBENA: Object to the form.</p>	<p>1 back, Vancomycin is the only one I remember. I think</p> <p>2 there's another one.</p> <p>3 Q. Have you seen anything suggesting that the</p> <p>4 drugs are Vancomycin, as you indicated, various forms</p> <p>5 of sodium chloride, dextrose and water? Is that</p> <p>6 consistent with your understanding?</p> <p>7 A. From what I remember yes. Generally.</p> <p>8 Q. And you were aware of the existence of the</p> <p>9 DOJAWPs while you were CMS administrator?</p> <p>10 MR. GOBENA: Object to the form.</p> <p>11 THE WITNESS: Yes. I was aware that they</p> <p>12 had been collected, and suggested to CMS. And at</p> <p>13 some point later, they would have been sent to the</p> <p>14 states.</p> <p>15 BY MR. DALY:</p> <p>16 Q. And if you turn to the attachments, the</p> <p>17 charts, I guess it would be page 6 of the document.</p> <p>18 Do you see --</p> <p>19 A. The attachments or --</p> <p>20 Q. The attachments. The charts. There is</p> <p>21 like -- there is little numbers up in the upper</p> <p>22 right-hand corner. I think those are the page</p>
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<p>1 THE WITNESS: I wasn't aware at the time.</p> <p>2 I've heard of it since.</p> <p>3 BY MR. DALY:</p> <p>4 Q. Okay. And did -- during your tenure or at</p> <p>5 any other time, are you aware of CMS directing that</p> <p>6 the states utilize the DOJAWPs for Medicaid</p> <p>7 reimbursement?</p> <p>8 MR. GOBENA: Object to the form.</p> <p>9 THE WITNESS: If they were, I'm not aware</p> <p>10 of it.</p> <p>11 BY MR. DALY:</p> <p>12 Q. And during your tenure with CMS, did you</p> <p>13 have any meetings with any representatives of DOJ or</p> <p>14 NAMFCU where the DOJ's AWPs were discussed?</p> <p>15 MR. GOBENA: Object to the form.</p> <p>16 THE WITNESS: Not that I'm aware of. I'm</p> <p>17 sure -- I'm fairly sure I did not.</p> <p>18 BY MR. DALY:</p> <p>19 Q. Did not. Okay. Are you aware of the</p> <p>20 drugs that the United States is suing Abbott for in</p> <p>21 this litigation?</p> <p>22 A. You know, I read the pleading a while</p>	<p>1 numbers.</p> <p>2 A. On the bottom.</p> <p>3 Q. If you go to page 6, you see --</p> <p>4 A. I don't see them on mine. Which chart is</p> <p>5 it?</p> <p>6 MR. GOBENA: This exhibit. Wrong exhibit.</p> <p>7 THE WITNESS: I'm sorry. I pulled that</p> <p>8 the wrong one. Too many charts of excessive drug</p> <p>9 prices. Yes.</p> <p>10 BY MR. DALY:</p> <p>11 Q. Okay. And in the -- on page 6, you see a</p> <p>12 variety of Abbott products. Do you see these various</p> <p>13 dextrose products?</p> <p>14 A. These are all Abbott. I wasn't aware of</p> <p>15 that. But yes, I see it.</p> <p>16 Q. And in terms of charts of excessive drug</p> <p>17 prices that you referred to, these are -- this is a</p> <p>18 chart that shows what the actual prices for some of</p> <p>19 those drugs were, correct?</p> <p>20 MR. GOBENA: Object to the form.</p> <p>21 THE WITNESS: I'm not aware of that. I</p> <p>22 assume so from the fact that it's a CMS carrier</p>

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1 directive. That's correct. 2 BY MR. DALY: 3 Q. And during your tenure, did you ever, if I 4 asked this forgive me, but did you ever have any 5 discussions with DOJ about the AWPs that they came up 6 with in this document? 7 MR. GOBENA: I'm going to object and 8 instruct the witness, you can answer the question 9 whether you had them, but I'm going to instruct him 10 not to answer about the substance of any 11 conversations as being covered by the attorney-client 12 privilege. 13 THE WITNESS: That's easy since I didn't 14 have any. 15 MR. GOBENA: It took me more words to say 16 my objection than for you to answer. 17 THE WITNESS: That's our goal for the rest 18 of the day. 19 BY MR. DALY: 20 Q. And do you have any information as to why 21 the United States and the Department of Justice 22 waited six years after putting forth the true AWPs on	1 why. I'm presuming that it was politics. I'm trying 2 to avoid the ones that created the greatest political 3 sensitivities which were the cancer drugs. 4 BY MR. DALY: 5 Q. Down further on page 2, the second to last 6 paragraph, there was a direction to the carriers that 7 essentially said that -- and you're welcome to read 8 it, either before or after I summarize it -- but 9 essentially says that if you get complaints from 10 providers about -- that these DOJAWPs are too low and 11 that the provider X can't get the drug for that 12 price, that they should either call one of the 13 wholesalers at the 800 number provided or call one of 14 the manufacturers. Do you see that language there? 15 A. Uh-huh. Yes. 16 Q. And would that have been a way to solve 17 the provider access problem? 18 MR. GOBENA: Object to the form. 19 THE WITNESS: Could have been a haphazard 20 way if you're giving the carriers discretion to 21 figure out to pay a reasonable price in their 22 judgment, which happens in many cases based on local
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1 this chart that the DOJ waited six years to unseal 2 the case against Abbott? 3 MR. GOBENA: Object to the form. Instruct 4 the witness not to answer to the extent the answer 5 goes into attorney-client communications. 6 THE WITNESS: I was unaware that it was 7 the case until I was called about the deposition. 8 BY MR. DALY: 9 Q. Now, on page 2 of the document, CMS 10 directed the carriers to consider some of the drugs 11 in setting reimbursement levels, but then with 12 respect to the drugs in attachment 2, the carriers 13 were directed that "you are not to consider at this 14 time using the DOJ data for these drugs." Do you see 15 that? The top paragraph? 16 A. Yes. Yes. 17 Q. And attachment 2 are 14 chemotherapy drugs 18 in three clotting factors. And my question is, do 19 you know why CMS directed that the carriers should 20 not consider the DOJAWPs for those drugs? 21 MR. GOBENA: Object to the form. 22 THE WITNESS: I do not -- I don't know	1 pricing, and make sure that providers can access the 2 drugs in a reasonable margin, I think it probably 3 would be one way to do it. But it's certainly not an 4 efficient way to do it. 5 There are other examples where I try to 6 figure out what the right price to charge is not an 7 easy process. So I mean, when I approved drug 8 eluting stents a few years back, I had my physicians 9 call around Europe to find out what companies were 10 charging there. Which was not a particular popular 11 way to do it, but it's the only place in the world 12 they were being sold, so it's not an easy -- if it 13 was easy to figure out the right price to pay, you 14 wouldn't be here. 15 BY MR. DALY: 16 Q. One of the problems that you had raised in 17 some of your testimony that we'll get to is that you 18 know if you simply reduce AWP to -- or I'm sorry, if 19 you reduce the reimbursement to, you know, 85 percent 20 or 80 or 75 percent of AWP or 50 percent of AWP, if 21 that's what the data is showing is the actual 22 acquisition costs on average, the problem with doing

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1 actually came out a couple days before you testified 2 on September 21st, is that your recollection? 3     A. In the Finance Committee. 4     Q. Pardon me? 5     A. In the Senate Finance Committee, that's 6 right. I'd have to look, but yes. After this, the 7 other testimony was in May. 8     Q. And if you'll turn to the second to last 9 page of this exhibit, you'll see a memorandum from 10 you to Laura Dummit. Do you see that? 11    A. Yes. 12    Q. And this is a memorandum indicating that 13 you received and had reviewed the report? 14    A. Yes. 15    Q. And in the narrative of your email -- or 16 I'm sorry, not email, but your memorandum to Laura 17 Dummit, you indicate that "the GAO confirms the 18 findings of its previous reports along with the 19 previous reports from the Office of the Inspector 20 General that Medicare payments for drugs are 21 substantially higher than the actual cost to 22 physicians and other providers acquiring these	1     A. Yes. 2     Q. And that was consistent with earlier 3 reports that you had seen, correct? 4           MR. GOBENA: Object to the form. 5           THE WITNESS: Yes. 6           BY MR. DALY: 7     Q. And then on page 9, if you'll turn to 8 that. 9     A. Okay. 10    Q. And this section is halfway down the page, 11 it's -- the caption is Medicare payments for drugs 12 are based on published AWPs. Do you see that? 13    A. Yes. 14    Q. And in the text, it says, "Medicare bases 15 its reimbursement to physicians and other providers 16 of drugs on AWP which is often described as a list 17 price, sticker price, or suggested retail price 18 reflecting the fact that AWP is not necessarily the 19 price paid by a purchaser or a consistently low or 20 wholesale price." Do you see that language? 21    A. Yes. 22    Q. And you agree with that, do you not?
1 drugs." Do you see that language? 2     A. Yes. 3     Q. And that's a reference to some of the 4 other reports that we have looked at and discussed 5 today, correct? 6     A. Yes. 7     Q. And so flipping back to the report itself 8 then, do you recall generally the findings of the 9 GAO, that coincided with your testimony? 10    A. Generally. 11    Q. Tell me. 12    A. I mean, I haven't read it in many years, 13 but I'm sure that they found it. 14    Q. It's summarized actually under results in 15 brief on page 4 of the document. 16    A. Yes. 17    Q. And in the first paragraph, about six or 18 seven lines down, it says, "for most physician 19 administered drugs, the average discount from AWP 20 ranged from 13 to 34 percent, two physician 21 administered drugs had discounts of 65 and 86 22 percent," do you see that?	1     A. Yes. 2     Q. If you turn to page 19 of the document, 3 Mr. Scully, I just wanted to ask a question. In the 4 middle of the -- or towards the end of the first full 5 paragraph, see the language that says, "we did not 6 analyze the costs of infusion therapy drugs provided 7 in the home setting because they do not account for a 8 substantial share of Medicare drug spending or 9 volume." Do you see that? 10    A. Yes. 11    Q. And what are infusion therapy drugs? 12    A. In the home setting. 13    Q. In the home setting. Yes. 14           MR. GOBENA: Object to the form. 15           THE WITNESS: Infusion therapy drugs, I'm 16 not sure what the most common ones are in the home 17 setting. But probably a small piece of the drugs. I 18 mean, in the home health setting, there are some 19 patients that go home and still have Lincare or 20 somebody deliver home health infusion drugs. 21           Vancomycin might be one of the higher 22 ones, I would think. Sometimes people go home from

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<p>1 the hospital and have antibiotics. So that might be      2 an example of that, but that's probably a much      3 smaller volume than nutritional outpatient drugs.      4 Maybe not for Vancomycin, but it would be for most      5 drugs. Certainly Procrit and some of the other      6 higher -- Remicade are generally done in a      7 physician's office or hospital outpatient      8 departments.</p> <p>9 BY MR. DALY:</p> <p>10 Q. And do you agree with the statement of the      11 GAO here that these drugs do not account for a      12 substantial share of Medicaid drug spending or      13 volume?</p> <p>14 MR. GOBENA: Object to the form.</p> <p>15 THE WITNESS: I don't know about volume,      16 but the biggest chunk of the -- by pure proportion is      17 oncology drugs, which is why the focus was oncology      18 and to a lesser degree rheumatology. In a reform      19 effort, but I'm not sure about volume and certainly      20 pure dollars spent, oncology is the dominant factor.</p>	<p>1 A. Lincare and Aprea I would say are probably      2 the two biggest companies. They do home delivery of      3 oxygen and respiratory supplies and home infusion.      4 So yes, if you're capable of going home and you need      5 some medications at home, they will deliver the      6 therapies at home.</p> <p>7 Q. And the home infusion business serves an      8 important purpose within the health care world      9 because it keeps people out of hospitals, correct?</p> <p>10 MR. GOBENA: Object to the form.</p> <p>11 THE WITNESS: Spend a couple of hours on      12 that. Yes, in theory, when it's run right, there is      13 a massive home health reform going on right during      14 this time, because home health itself had had some      15 pretty significant reimbursement issues. And      16 probably the biggest set of provider enforcements of      17 the '90s were home health providers. So there was      18 certainly a lot of inappropriate behavior going on in      19 home health certainly in the early '90s.</p> <p>20 BY MR. DALY:</p> <p>21 Q. But in theory, I think you said one of the      22 advantages of being able to provide care for people</p>
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<p>1 states at the very top that "in conducting this      2 study, we interviewed officials at CMS, VA, HHS, OIG      3 and DOJ." Do you see that?</p> <p>4 A. Yes.</p> <p>5 Q. Did they meet with you at all?</p> <p>6 A. I don't remember that they did, and my      7 guess is that I probably wasn't in office confirmed      8 by the time they actually finished doing the research      9 on this. If they put it out in September and I came      10 in May. But I don't remember meeting with them.</p> <p>11 Q. And back to the business of the home --      12 the home infusion drugs, I mean what -- I just want      13 to understand how that part of the business operates.      14 Home infusion is for folks who are able to be treated      15 at home for whatever it is that they are suffering      16 from?</p> <p>17 A. Yes.</p> <p>18 Q. And there are home infusion companies, for      19 example?</p> <p>20 A. Yes. The two biggest are probably Lincare      21 and Aprea.</p> <p>22 Q. And what's the second one?</p>	<p>1 in their homes is that they don't have to have the      2 burden of being in the hospital and the costs      3 associated with hospitalization, correct?</p> <p>4 A. In theory.</p> <p>5 MR. GOBENA: Object to the form.</p> <p>6 BY MR. DALY:</p> <p>7 Q. In theory, yes?</p> <p>8 A. In theory, that's probably correct, yes.</p> <p>9 And that the patients prefer it.</p> <p>10 MR. GOBENA: Same objection.      (Exhibit Abbott 187 was      marked for identification.)</p> <p>11 BY MR. DALY:</p> <p>12 Q. Mr. Scully, I've handed you what we've      13 marked as Exhibit Abbott 187, which is a copy of your      14 live testimony before the Committee on Energy and      15 Commerce September 21, 2001. Is that what you      16 recognize it to be?</p> <p>17 A. Yes.</p> <p>18 Q. If you turn to page 83 -- I mean, this      19 document starts on 82, but page 83 of this particular      20 record, it's the second page of the document. Do you</p>

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<p>1 Q. I'm not complaining or criticizing what 2 you did.</p> <p>3 A. When I started trying to fix this, the 4 vast bulk of people told me I was on a suicide 5 mission and that it was crazy. And I did get it 6 fixed, and it was largely because we operated in the 7 political milieu that we had.</p> <p>8 Q. And my question was simply that you had 9 access to AMP information, right?</p> <p>10 A. Yes.</p> <p>11 Q. And in fact, CMS had had access to AMP 12 information ever since the Medicaid rebate program 13 went into effect in 1991 or 1992, right?</p> <p>14 MR. GOBENA: Objection to form.</p> <p>15 BY MR. DALY:</p> <p>16 Q. True?</p> <p>17 MR. GOBENA: Objection to form.</p> <p>18 THE WITNESS: Yes. In the format it was 19 coming in which was somewhat flawed.</p> <p>20 BY MR. DALY:</p> <p>21 Q. And your view was that while not perfect, 22 AMP information approximated ASP, correct?</p>	<p>1 knowledge, the manufacturers were never asked to 2 report something lower than AWP that would be used 3 for reimbursement?</p> <p>4 MR. GOBENA: Objection to form.</p> <p>5 BY MR. DALY:</p> <p>6 Q. Correct? During the 1990s and into at 7 least through the end of your administration?</p> <p>8 MR. GOBENA: Same objection. Asked and 9 answered.</p> <p>10 THE WITNESS: I'm not aware of any efforts 11 specifically like that outside of surveys.</p> <p>12 BY MR. DALY:</p> <p>13 Q. Let's turn to -- what exhibit are we on 14 now? Exhibit Abbott 191. Turn to page 14.</p> <p>15 A. Okay.</p> <p>16 Q. And 14 is, I believe, a letter or some 17 other submission that you made to the committee, is 18 that correct?</p> <p>19 A. I assume. I haven't seen this before.</p> <p>20 Q. Well, if you take a look at pages 14 and 21 15, there is -- it's dear Chairman Johnson, and then 22 it's signed on page -- not signed, but indicates that</p>
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<p>1 A. The concept was similar.</p> <p>2 Q. Okay. And my only question was whether 3 you or any of your predecessors at CMS ever went to 4 the manufacturers and said, hey, I got your AMP, we 5 know that your AWP is substantially higher or vastly 6 higher, or as you put in your testimony, pretty much 7 air. And we all know that, and what we'd like you to 8 do is to report a lower AWP. Did you or any of your 9 predecessors ever do that?</p> <p>10 MR. BREEN: Objection to form.</p> <p>11 MR. GOBENA: Objection, form.</p> <p>12 BY MR. DALY:</p> <p>13 Q. Go ahead.</p> <p>14 A. I think the record shows that both the 15 Clinton Administration tried through various 16 mechanisms to do surveys, get reports, get the 17 carriers to lower their prices. And they 18 consistently got, I believe from an undereducated 19 Congress, a lot of push back. And they consistently 20 dropped those efforts. Including a moratorium for 21 one year from Congress on doing anything.</p> <p>22 Q. So the answer to my question, to your</p>	<p>1 it's from you on page 15. Do you see that?</p> <p>2 A. Yes.</p> <p>3 Q. And you know you can take a moment to look 4 at it, but is this a written submission that you made 5 to Chairman Johnson?</p> <p>6 A. It certainly looks like it.</p> <p>7 Q. And on the page 14, and you talk under the 8 heading form of administration, you say, "22 of the 9 35 drugs, accounting for 38 percent of carrier 10 spending are administered by intravenous infusion." 11 Do you see that?</p> <p>12 A. Yes.</p> <p>13 Q. And this would include all of the drugs 14 that are administered through intravenous infusion 15 correct?</p> <p>16 MR. GOBENA: Object to the form.</p> <p>17 BY MR. DALY:</p> <p>18 Q. All of the drugs covered by Medicare Part 19 B. Go ahead.</p> <p>20 A. That's what -- yes. Intravenous infusion. 21 Part B only covers drugs that are not usually 22 self-injected, is the definition.</p>

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<p>1 Q. And we had looked at this earlier, in the      2 context of the GAO report that came out in September      3 of '01, there was that indication on page 19 that the      4 GAO had not researched the infusion drugs because      5 they were a small part of the Medicare Part B pie.      6 Do you recall that?</p> <p>7 MR. GOBENA: Objection.</p> <p>8 THE WITNESS: Home infusion.</p> <p>9 BY MR. DALY:</p> <p>10 Q. Home infusion. And when you talk about      11 intravenous infusion here, that would include the      12 home infusion drugs as well, wouldn't it?</p> <p>13 A. I don't know, to be perfectly honest with      14 you. The bulk of the drugs and the bulk of the      15 spending is physician office and outpatient infusion.      16 So home health infusion, which is usually the same      17 drugs, may or may not be. I'm not sure.</p> <p>18 Q. And are you aware of whether or not for      19 home infusion that Medicare provides any kind of      20 service fee for the administration of home infusion      21 drugs?</p> <p>22 MR. BREEN: Objection. Form.</p>	<p>1 rheumatology and other physician office drugs.</p> <p>2 Q. So does that mean you don't --</p> <p>3 A. So after I left, and after the bill went      4 into effect, the home health providers came in and      5 raised quite a ruckus about the lack of dispensing      6 fee mainly for inhalation drugs, but also I believe      7 for home health infusion. And CMS did in fact      8 basically create a home -- at least for respiratory      9 drugs, and I assume it was for infusion as well, a      10 dispensing fee for those drugs, which again similar      11 to oncology, was a small -- the increase they created      12 for dispensing the drugs was a small piece of the AWP      13 drug savings in that arena, I believe.</p> <p>14 Q. So it's your understanding that prior to      15 the MMA, there was no separate service fee for home      16 infusion?</p> <p>17 A. I may be wrong, but I don't think there      18 was.</p> <p>19 Q. Okay. And when the MMA was instituted,      20 you know, as a result of your efforts, there was no      21 provision in that act for a service fee for home      22 infusion either, is that what you're saying?</p>
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<p>1 THE VIDEOGRAPHER: I'm sorry. Who made      2 that objection?</p> <p>3 MR. BREEN: Breen.</p> <p>4 MR. GOBENA: You can answer.</p> <p>5 THE WITNESS: Prior to --</p> <p>6 MR. DALY: If they just object on form,      7 just go right ahead.</p> <p>8 THE WITNESS: Prior to the CMS change      9 after they went did the AWP reform, I don't believe      10 there was any service fee for home infusion or home      11 inhalation delivery. And I believe there is now.      12 But there was no service fee at the time.</p> <p>13 BY MR. DALY:</p> <p>14 Q. And I'm just looking at your answer here      15 on the screen. Prior to CMS change, after they went      16 to the AWP form -- I'm not sure if I'm understanding.      17 Can you just expand on that a little bit?</p> <p>18 A. After we changed the AWP to ASP plus 6 in      19 the 2003 bill, there was very little to zero      20 discussion and/or thought about any of the home      21 health drugs. It was generally not a discussion of      22 the vast bulk of the spending was in oncology and</p>	<p>1 A. I'm pretty sure there was not.</p> <p>2 Q. And that subsequent to the institution of      3 the MMA, that's when the home health providers came      4 forward and something was done to rectify that?</p> <p>5 A. And it was done on --</p> <p>6 MR. GOBENA: Objection to form. Sorry.      7 Go ahead.</p> <p>8 THE WITNESS: I know it was done for      9 respiratory drugs. I believe it was for infused      10 drugs as well. I'm not sure, but I'm pretty -- I      11 know respiratory drugs it was. And I was actually --      12 it was just something that was not considered in      13 2003. And CMS, I think, decided that was an      14 inadvertent error and they put in a dispensing fee      15 for infusion drugs -- I mean, for respiratory drugs.      16 I'm not sure -- I'm fairly certain it covered      17 infusion as well.</p> <p>18 BY MR. DALY:</p> <p>19 Q. And prior to something being done about      20 that after the MMA was put into effect, is it your      21 understanding that the home infusion care providers      22 were relying on the spread between their acquisition</p>

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<p>1 costs and AWP to fund the services that they were 2 providing?</p> <p>3 MR. GOBENA: Objection. Form.</p> <p>4 THE WITNESS: I assume that that was part 5 of how they paid for the cost of delivering the 6 services. Yes.</p> <p>7 (Exhibit Abbott 192 was 8 marked for identification.)</p> <p>9 BY MR. DALY:</p> <p>10 Q. Mr. Scully, I've handed you what we've 11 marked as Exhibit Abbott 192, bearing Bates stamp 12 numbers HHC 0030446 through 0449, which is a letter 13 from the -- excuse me, Long-Term Care Pharmacy 14 Alliance to you. And do you recognize this letter?</p> <p>15 A. No.</p> <p>16 Q. In the first paragraph, it says, "I am 17 writing," this is a letter dated July 22, 2002. And 18 it is, it says in the first sentence, "I am writing 19 to thank you for taking the time to meet with us on 20 June 27." Do you see that?</p> <p>21 A. Yes.</p> <p>22 Q. Do you have any recollection of meeting</p>	<p>1 the prices at which we purchase a drug and the 2 average wholesale price of the drug." Do you see 3 that language?</p> <p>4 A. Yes.</p> <p>5 Q. And do you have an understanding that that 6 is a correct statement?</p> <p>7 MR. GOBENA: Objection to form.</p> <p>8 THE WITNESS: Yes. I mean, I think the 9 issue is a matter of proportion. It's similar to the 10 oncologists, which is they clearly made money on the 11 spread and how much of that -- what measurement 12 appropriately should have been paid to deliver the 13 service, some portion of it. I don't know enough 14 about the nursing home issue here to know how much 15 there was. This is a small -- you know, nursing 16 homes are similar to home infusion, where they have 17 Part B Medicare patients in the home, and they 18 provide the service and they get paid for it.</p> <p>19 So how much did they make on AWP spread 20 and how much of that would have measurably been put 21 back in if they had a more rational policy into a 22 servicing fee? I'm not sure, but my guess is much</p>
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<p>1 with representatives of the LTCPA in June of -- or 2 the summer of 19 -- or of 2002?</p> <p>3 A. No.</p> <p>4 Q. No. You meet with a lot of people, 5 though?</p> <p>6 A. I met with a lot of people.</p> <p>7 Q. Have you ever heard of the LTCPA?</p> <p>8 A. Vaguely.</p> <p>9 Q. Okay. And you understand them to be some 10 sort of trade association for home infusion?</p> <p>11 A. I thought it was a trade association for 12 nursing home pharmacists, so there may be home 13 infusion people in it, but I think it's nursing home 14 pharmacists. Maybe I'm wrong about that, but I think 15 that's what it is. The trade association for most of 16 the home infusion people is AA Home Care, I think, a 17 different group.</p> <p>18 Q. The bottom of the first page, they say in 19 their letter to you, "right now, most of the 20 reimbursement for the special services provided by 21 long-term care pharmacies is implicit. That is to 22 say, we find our reimbursement in the spread between</p>	<p>1 like oncology, it probably wouldn't be all of it. 2 And I don't have all the facts to tell you that. I 3 mean, I did know on the dialysis side, it probably 4 was appropriate to put all of it back in. In many 5 other settings, it was not.</p> <p>6 BY MR. DALY:</p> <p>7 Q. I'm going to hand you what's been 8 previously marked as Exhibit Abbott 018, which 9 is testimony that was submitted at the hearing that 10 we've been talking about on October 3, 2002 that you 11 attended by the National Alliance for Infusion 12 Therapy and the National Home Infusion Association. 13 And do you recall the presentation that these 14 entities made at the hearing on 10-3-02?</p> <p>15 A. No. I'm sure I wasn't there.</p> <p>16 Q. Well, you were there for your part. This 17 is the same hearing you were at.</p> <p>18 A. I traditionally left as soon as I was 19 done.</p> <p>20 Q. As soon as possible.</p> <p>21 A. As did every other administrator.</p> <p>22 Q. Now, did you ever have any meetings or</p>

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<p>1 correspondence with either of these entities      2 concerning their concerns relating to proposed      3 amendments to the Medicare reimbursement structure?</p> <p>4       A. Not that I remember. They were not major      5 players.</p> <p>6       Q. And if you drop down to the, on the first      7 page under Medicare coverage and payment for home      8 infusion drug therapy, do you see that?</p> <p>9       A. Yes.</p> <p>10      Q. In the first sentence, they say,      11 "providers and suppliers of infusion drug therapies      12 in the home setting are not paid separately by      13 Medicare for the critical services and practice      14 expenses described above." Do you see that?</p> <p>15      A. Yes.</p> <p>16      Q. And that's, I take it, having discussed it      17 with you earlier, that's consistent with your      18 understanding, that they were not receiving a      19 separate reimbursement for services on the home      20 infusion front, is that correct?</p> <p>21      MR. GOBENA: Objection to form.</p> <p>22      THE WITNESS: I don't believe -- I do not</p>	<p>1 their AWP margins, and how big were they, and were      2 they appropriate or not, and what should have been      3 added back as far as I know, it never came up.</p> <p>4           BY MR. DALY:</p> <p>5        Q. So the -- as you said, these -- this group      6 was this group being the home infusion caregivers,      7 they were ignored in the legislation you were working      8 on, correct?</p> <p>9           MR. GOBENA: Objection. Asked and      10 answered.</p> <p>11          THE WITNESS: On AWP, I would say that is      12 correct. They had other -- some of the members and      13 manufacturers had other issues. And the noise from      14 the oncologists was very loud. And obviously this is      15 part of the Medicare drug benefit, which is a very      16 big, very controversial bill. And I don't think any      17 of us really thought about these guys, to be      18 perfectly honest, until after the bill passed.</p> <p>19           BY MR. DALY:</p> <p>20        Q. Now --</p> <p>21        A. In four months in the Medicare conference      22 committee, and I don't think I missed any of it, or</p>
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<p>1 believe they were getting a separate payment for      2 services. Yes.</p> <p>3           BY MR. DALY:</p> <p>4        Q. And as they say here, continuing in that      5 paragraph, the only items that we -- "the only items      6 that are explicitly covered and reimbursed under this      7 limited benefit are the drugs, equipment and      8 supplies," do you see that?</p> <p>9        A. Yes.</p> <p>10       Q. And that, based on your recollection of      11 the circumstances, appears to be a correct statement,      12 right?</p> <p>13        MR. GOBENA: Objection to form.</p> <p>14        THE WITNESS: Yes. And I would say while      15 I'm not qualified to do it here and obviously we      16 completely ignored these guys in the legislation,      17 there was a thorough discussion on the oncology side      18 that the AWP margins were far more than needed on the      19 practice expense add back by whatever I said, 1 to 20      20 or 1 to 5. On dialysis, it was 1 to 1. And for      21 these guys, it was never discussed.</p> <p>22        So what's the appropriate -- what were</p>	<p>1 whatever you want to call it, the quasi conferences,      2 it was, you know, Senator Baucus and Senator Roe and      3 Republican members on both sides. I don't remember      4 this ever coming up.</p> <p>5        Q. And what you said earlier is that you      6 believe that with respect to home infusion, that the      7 situation was addressed after the MMA was put into      8 place and after you had left the administration,      9 correct?</p> <p>10        MR. GOBENA: Objection to form.</p> <p>11        THE WITNESS: I should know this, but      12 there was -- I don't know on home infusion. I assume      13 it was. I know on respiratory therapy drugs, there      14 was a dispensing fee created administratively by CMS      15 the following year on the argument, for the      16 respiratory drugs, that there was no margin left, and      17 the service wouldn't be provided.</p> <p>18        So CMS created a dispensing fee, which I      19 believe was 55 bucks or something for the first 60      20 days, and then it went down from there. I think it's      21 now down to 28, it was phased down. But for      22 respiratory therapy, there was a dispensing fee</p>

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<p>1 created by CMS in 2004 by regulation, to deal with      2 this. I assume it was done for infusion as well, but      3 I don't know, to be honest with you.</p> <p>4 BY MR. DALY:</p> <p>5 Q. As part of the MMA, were some drugs kept      6 at 95 percent of AWP? When I say kept at, was      7 reimbursement kept at 95 percent of AWP?</p> <p>8 A. I think I may be wrong, but I think maybe      9 some IVIG. Something was. I can't remember what.</p> <p>10 Q. And what would that stand for?</p> <p>11 A. Intravenous immune suppressant, I forget      12 what the G is, but it's a -- it's a fairly widely      13 used immune deficiency set of -- I guess they are      14 theoretically drugs or biological therapies. I think      15 that's the only one, IVIG. I may be wrong. You may      16 be aware of it. I'm not sure. There were a couple      17 of carveouts. I can't remember exactly what.</p> <p>18 (Exhibit Abbott 193 was      19 marked for identification.)</p> <p>20 BY MR. DALY:</p> <p>21 Q. And the court reporter is handing --</p> <p>22 A. Which reminds me my law firm does work for</p>	<p>1 And if you flip over to subparagraph five      2 on the third page of the document, it states that      3 "payment limits for infusion drugs furnished through      4 a covered item of durable medical equipment on or      5 after January 1, 2004 are 95 percent of the AWP      6 reflected in the published compendia as of October 1,      7 2003, regardless of whether or not the durable      8 medical equipment is implanted." Do you see that      9 language?</p> <p>10 A. Yes.</p> <p>11 Q. And do you recall working on a carveout      12 from the ASP plus 6 or the 85 percent of AWP that was      13 part of the MMA in January of 2004?</p> <p>14 A. I was gone.</p> <p>15 Q. Well, this, this -- well, I'm asking you,      16 did you work on this?</p> <p>17 A. 2004. I was gone.</p> <p>18 Q. This is like a few weeks after you left.</p> <p>19 A. Yes. No. I don't. I pretty much -- the      20 bill passed and I was -- you know, the bill passed in      21 December and I was pretty -- declared to be heading      22 for the exits. I had basically stayed to get the</p>
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<p>1 CLB, which is an IVIG company. Just remembered when      2 I answered your question. They have a very narrowly      3 tailored series of drugs.</p> <p>4 Q. I've handed you what the court reporter      5 has marked Exhibit Abbott 193, and it's a CMS manual      6 system document that's entitled some sort of change      7 request. And without going into the details of this      8 particular document, Mr. Scully, what is, what is      9 this CMS manual system?</p> <p>10 A. What is the manual system? It's a      11 subregulatory director -- directive to carriers and      12 fiscal intermediaries and CMS contractors just how to      13 carry out.</p> <p>14 Q. So this is going out to carriers telling      15 them what to do?</p> <p>16 A. It's generally available to providers as      17 well depending on their area.</p> <p>18 Q. And if you'll turn to -- well, turn to the      19 second page of the document, it's talking about the      20 MMA, and appears to be talking about certain drugs      21 that are going to be kept at 95 percent of AWP for      22 reimbursement purposes.</p>	<p>1 bill passed probably six months longer than I      2 originally planned. So no, I don't remember this.      3 It does appear if there was a carveout -- so what      4 you're saying is for DME drugs, infused home drugs,      5 there was a carveout for 95 percent of the bill.</p> <p>6 Q. That's what I'm asking. That's what it      7 looks like to me. I'm asking you.</p> <p>8 A. I don't remember that. But it appears      9 that there was in the statute, but I just don't      10 recall. It may have been, we had many issues in the      11 bill.</p> <p>12 Q. So this carveout was not something that      13 you would have discussed with staff in December or      14 November or October of 2003?</p> <p>15 A. I don't remember. It was in the      16 legislation? It must have been if it's in here.      17 There was a carveout of the legislation for home      18 infused drugs?</p> <p>19 Q. That's what it suggests. Yes.</p> <p>20 A. Well, I just don't have the legislation in      21 front of me, but I'm sure if that was, it was done      22 for a reason. And I'm -- I just don't remember if</p>

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<p>1 there was a carveout. If it was, they probably      2 carved it out for the reasons I discussed because      3 there was no dispensing fee.</p> <p>4 Q. Because of what?</p> <p>5 A. I'm assuming if there is a carveout for      6 home infusion drugs, it was done largely for that      7 reason.</p> <p>8 Q. Because there was no dispensing fee is      9 that what you said?</p> <p>10 A. But I was not aware of that until you      11 showed it to me. If I was -- I may have been aware      12 at the time, but I had forgotten. It's not something      13 that I discussed widely with the staff at the time.</p> <p>14 MR. GOBENA: I'm going to object to this      15 line of questioning, to the extent you're saying      16 there was a carveout beyond December 31st, 2004. If      17 you look at the second page, it covers the time      18 period for which this memorandum is operative.</p> <p>19 BY MR. DALY:</p> <p>20 Q. When did you leave?</p> <p>21 A. January 4th was my last day, 2004.</p> <p>22 Q. That's when you left CMS. Correct?</p>	<p>1 BY MR. DALY:      2 Q. Well, at least for a year.      3 A. I think there was a one-year transition      4 for a few things. I just don't remember which --      5 clotting factor, I know, was one. If we did it for      6 home infusion drugs, I forgot.</p> <p>7 Q. And it would appear based on Exhibit      8 Abbott 193 that it was also at least a one-year      9 carveout for infusion drugs that are delivered      10 through DME, correct?</p> <p>11 MR. GOBENA: Object to the form.</p> <p>12 THE WITNESS: If I remember for that      13 entire one year, we also had 85 percent of AWP. We      14 didn't get ASP plus 6 until a year later either.</p> <p>15 BY MR. DALY:</p> <p>16 Q. Right.</p> <p>17 A. Right? So there was a one-year modest cut      18 from AWP and then a transition to ASP plus 6, right?</p> <p>19 Q. I believe that was the sequence. And so      20 for this first year, according to this, these drugs      21 issued in a home care setting through a DME, durable      22 medical equipment, would stay at 95 percent of AWP</p>
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<p>1 A. Yes. I believe that's the right final      2 day.</p> <p>3 Q. And if you look at the, if you look at the      4 attachments, there is the addendum F, which is the      5 list of drugs, are you saying you have no      6 recollection of this during your tenure with CMS?</p> <p>7 A. It's vaguely coming back to me that we did      8 some carveouts for blood -- for clotting factors. I      9 wasn't aware we did it for home infusion drugs. If      10 there is a home infusion carveout in the bill, I have      11 just forgotten it. There may have been. I knew we      12 did one for clotting factors, and just looking at      13 this rule, it was largely Senator Grassley's staff      14 that was doing this. So I should be aware of it, but      15 I just -- was it a one-year provision or a permanent      16 one? I just don't remember.</p> <p>17 Q. Well, I mean, I think this thing changed      18 over time, but certainly this is talking about it      19 being in effect for -- effective January 1, 2004      20 according to the addendum.</p> <p>21 A. Yes.</p> <p>22 MR. GOBENA: Through December 31, 2004.</p>	<p>1 for the reimbursement, correct?</p> <p>2 A. As the clotting factor and the rest went      3 to 85? You remember -- I had forgotten, but I guess      4 that's right.</p> <p>5 Q. Okay. And that would be with knowledge      6 that the ASP for these drugs was much lower than 95      7 percent of AWP, correct?</p> <p>8 MR. GOBENA: Object to the form.</p> <p>9 THE WITNESS: Obviously, I don't have a      10 great recollection of this particular issue and how      11 it was treated legislatively. It was not -- it was      12 not one of the top 200 issues I was dealing with.</p> <p>13 BY MR. DALY:</p> <p>14 Q. But you knew, for example, that -- you      15 know, I think you use it in your -- as an example in      16 some of your testimony, that the AWP for Vancomycin,      17 for example, was higher than the ASP for Vancomycin,      18 correct?</p> <p>19 A. Yes.</p> <p>20 Q. And so if this exception was going to      21 treat Vancomycin and allow it to be reimbursed at 95      22 percent, it would -- of AWP, it would be, that would</p>

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<p>1 be a level that was much higher than the ASP for      2 Vancomycin, correct?</p> <p>3 MR. GOBENA: Objection. Form. Also going      4 to object to the previous question. I didn't get a      5 chance to get in there. Object to the form on that.      6 You can answer the question.</p> <p>7 THE WITNESS: Yes. My guess would be      8 obviously it was a transition for one year to 85      9 percent of AWP for all drugs, 95 percent for clotting      10 factor and some other drugs. And I'm sure they      11 didn't go through drug by drug and look at the      12 margins. I assume there were other home health      13 infusion drugs, for which they felt the margins for      14 that one year may have been sensitively narrow, and      15 so they kept it at 95 percent.</p> <p>16 I'm just guessing -- just remember, my      17 testimony for Vancomycin, the spread was pretty big      18 and there probably wasn't a whole lot of worry about      19 85 percent not being big enough to cover it, so it's      20 probably not the reason that drove the policy.</p> <p>21 (Exhibit Abbott 194 was      22 marked for identification.)</p>	<p>1 right?      2 BY MR. DALY:      3 Q. I believe that's right.      4 (Exhibit Abbott 195 was      5 marked for identification.)      6 THE WITNESS: Good heavy one. I can take      7 care of the rest of those if you like.      8 BY MR. DALY:      9 Q. And you mentioned that, you know, this      10 might have been a one-year carveout. And Mr. Gobena      11 seems anxious to point that out. Taking a look at      12 Exhibit Abbott 195, which I've handed you, this is      13 certain amendments that went into effect with respect      14 to the MMA effective December 20, 2006. Do you see,      15 do you see that?</p> <p>16 A. Yes.      17 Q. And if you would turn to page 21 of this      18 document, and subparagraphs D-1 and D-2. Do you see      19 that the carveout that we identified that was in      20 effect for 2004 remains in effect today?</p> <p>21 MR. GOBENA: Object to the form. Excuse      22 me.</p>
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<p>1 BY MR. DALY:      2 Q. And Mr. Scully, I've handed you what the      3 court reporter has marked as Exhibit Abbott 194,      4 which is a copy of at least portions of the MMA      5 itself. And I would ask you to turn to page 23 of      6 that document. And you had asked whether this was a      7 carveout in the legislation itself, and I just want      8 to direct you to page 23 at the bottom, subparagraphs      9 D-1 and 2.</p> <p>10 A. Okay.      11 Q. And does that appear to be the legislative      12 carveout for the rule that we were just looking at?      13 A. Refreshing my memory, I had forgotten we      14 did that. Yes.</p> <p>15 MR. GOBENA: While Mr. Daly is getting his      16 exhibit out, I'll note the first page, it says that      17 this piece of legislation was effective December 8,      18 2003 to December 31, 2004.</p> <p>19 MR. DALY: Anything else you want to point      20 out?</p> <p>21 THE WITNESS: Yes. This was a one-year      22 transition. It went to ASP plus 6 in 2004, is that</p>	<p>1 THE WITNESS: Yes. I wasn't aware of      2 that, so there is still -- they're still 95 percent      3 of AWP today?      4 BY MR. DALY:      5 Q. That's what the statute says, isn't it?      6 A. Yes. I wasn't aware of that. That's what      7 the statute says.      8 MR. BREEN: Just for clarification,      9 Mr. Daly, are you referring to subparagraph D little      10 I, which ends with 95 percent of the average      11 wholesale price for such drug in effect on October 1,      12 2003?      13 MR. DALY: And D-2.      14 MR. BREEN: Say again?      15 MR. DALY: And the next paragraph, D      16 Romanette i and D Romanette ii.      17 THE WITNESS: Until they froze it at the      18 date of passage, October -- they picked the -- 95      19 percent of the AWP in place in October 2003, and      20 froze it. I had forgotten that.      21 BY MR. DALY:      22 Q. And so at least for the drugs that are</p>

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1 subject to this carveout in the home infusion 2 setting, Congress has kept the reimbursement of those 3 drugs at 95 percent of AWP as of -- 4     A. As of October 2003. 5     Q. That's correct, isn't it? 6     A. I guess it is. That's what the statute 7 says. Another piece of sausage. I have just 8 forgotten that we did that, to be honest with you, 9 which I assume is why they don't have a dispensing 10 fee for anything but respiratory drugs, because they 11 didn't do that for respiratory drugs. 12     Q. So it would appear that Congress, at least 13 for these drugs and in that setting of home infusion, 14 has determined to continue to subsidize the provision 15 of the services by overpaying for the drugs, correct? 16     MR. GOBENA: Objection to the form. The 17 legislation speaks for itself. 18     MR. BREEN: Objection to the form. 19     BY MR. DALY: 20     Q. You can go ahead. 21     A. Yes. I was surprised to see this. I 22 forgot we did it. It was certainly never discussed	1 to page 27. 2     A. 27? 3     Q. Yes. 4     A. Okay. 5     Q. And in your testimony in response to 6 Mr. English, you indicate that you think -- well, you 7 state, "I think there are a lot of different provider 8 areas that may have small impacts from AWP, and we 9 are certainly willing to work with the committee to 10 identify those." And then you mentioned oncology 11 as -- oncology and dialysis and hematology being sort 12 of the big three, right? 13     A. Yes. 14     Q. And then you say, "I think almost every 15 physician to some degree that administers drugs 16 probably has some beneficial cost shifting benefit 17 from AWP, I think those are the three big areas," you 18 see that language? 19     A. Yes. 20     Q. And that was a true statement, correct? 21     A. Yes. 22     Q. On page 31, I just want to get a fix for
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1 by members. I'm sure the staff -- staff person who 2 wrote it works with me at Alston & Bird, so I'll go 3 back and ask him, but I'm sure that it's probably, 4 they froze it to freeze it, and some level of 5 cross-subsidy apparently. I'm not sure what the 6 congressional intent there was, but I think it was 7 Senator Grassley's staff that did that provision. So 8 I had totally forgotten we did it. That it was in 9 the bill. It wasn't something that was widely 10 discussed at all. 11     Q. And are you aware of whether the drugs 12 that DOJ is suing Abbott for, many of those drugs are 13 used in the home infusion context and using DME? 14     MR. GOBENA: Objection to form. 15     THE WITNESS: As of today, I'm aware of 16 it. I wasn't aware of it before. 17     BY MR. DALY: 18     Q. But as of today, you are? 19     A. Yes. Obviously looking at the drug list. 20     Q. Page 27 of Exhibit Abbott 191, which is 21 your 10-3 -- yes, your October 3 -- excuse me, 22 October 3, 2002 testimony. I just want to direct you	1 -- and we may have covered this in some part in the 2 sort of background section that we did at the 3 beginning, but you state at the bottom of the page, 4 "I had been working on Medicare for over 20 years and 5 there has never been any law passed more complicated 6 than this one." How far back does your work on 7 Medicare go? 8     A. In a minor way, probably 1982. But in a 9 full time way, 1989. 10     Q. And what were you doing with respect to 11 Medicare in 1982? 12     A. Not much. Occasional staff work for 13 Senator Gorton, but very, you know, minor. 14     Q. And '89 would have started your work with 15 the Bush Administration? 16     A. And OMB. Yes. 17     Q. And if you would turn to page 34. If you 18 -- actually, if you look at 33, the page before, it 19 looks like you finished up your testimony, and then 20 George Reeb, R-E-E-B, got in the hot seat. And began 21 to talk a little bit about Medicare and Medicaid. 22 And on page 34 of Mr. Reeb's testimony, he states

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<p>1 that "this occurs largely because Medicare and 2 Medicaid base reimbursement to physicians and 3 suppliers on inflated average wholesale prices." Do 4 you see that language?</p> <p>5 A. Where is that? I'm sorry.</p> <p>6 Q. I'm sorry?</p> <p>7 A. Where is it, second --</p> <p>8 Q. I think it's the second full sentence on 9 page 34.</p> <p>10 A. Oh, yes. Okay.</p> <p>11 Q. Do you see that language?</p> <p>12 A. Yep. I'm getting tired so --</p> <p>13 Q. And in the -- I know the feeling. And in 14 the Medicaid world, as we talked briefly earlier, 15 Medicaid state agencies are reimbursed typically on 16 some formula of AWP minus a certain percent or 17 sometimes, for example, WAC plus a certain percent, 18 is that your general understanding?</p> <p>19 MR. GOBENA: Objection to the form.</p> <p>20 THE WITNESS: Yes. It is.</p> <p>21 BY MR. DALY:</p> <p>22 Q. And here, in the -- in this next</p>	<p>1 this hearing pertains to Medicare, I would also like 2 to mention our work on Medicaid primarily because it 3 confirms that AWP is not a realistic basis for drug 4 reimbursement." Do you see that language?</p> <p>5 A. Yes.</p> <p>6 Q. And do you agree with that statement, in 7 the Medicaid context?</p> <p>8 A. Yes. For the most part. I would add the 9 state situation is much more complex, because of 10 rebates which doesn't happen in Medicare. The states 11 get rebates on Medicaid and so the price they 12 actually pay is complicated by the rebates they get 13 back.</p> <p>14 Q. In the next sentence, it states, "in 15 Medicaid, we found that there was a significant 16 difference between the pharmacy acquisition costs for 17 drugs and their published AWPs. In our latest report 18 we found that pharmacy acquisition costs ranged from 19 17 to 72 percent below published AWPs." Do you see 20 that?</p> <p>21 A. Yes.</p> <p>22 Q. And was that a caution of concern for you?</p>
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<p>1 paragraph, there is discussion of Medicare 2 reimbursing physicians at 95 percent of AWP. That 3 was the law prior to the institution of the MMA, 4 correct?</p> <p>5 MR. GOBENA: Object to the form.</p> <p>6 THE WITNESS: Yes.</p> <p>7 BY MR. DALY:</p> <p>8 Q. Okay. And in the next sentence, it says, 9 "similarly, state Medicaid agencies reimburse 10 pharmacies at AWP minus an average of 10.3 percent." 11 Do you see that?</p> <p>12 A. Yes.</p> <p>13 Q. And is that consistent with your 14 understanding of the discounts that states were 15 typically reimbursing their pharmacy purchases at?</p> <p>16 MR. GOBENA: Object to the form.</p> <p>17 THE WITNESS: I don't recall. I'm 18 guessing GAO must be -- or the IG must be close to 19 correct. That's probably a wide average.</p> <p>20 BY MR. DALY:</p> <p>21 Q. Couple paragraphs down, maybe three 22 paragraphs down the statement, it says, "although</p>	<p>1 MR. GOBENA: Object to the form.</p> <p>2 THE WITNESS: Yes. As I said, as I 3 explained earlier today, you know, we could help 4 share information with the states, but Medicaid is a 5 state managed program. And the states had the right 6 to negotiate whatever price they thought was 7 appropriate.</p> <p>8 BY MR. DALY:</p> <p>9 Q. Within reason, right?</p> <p>10 A. Within reason.</p> <p>11 Q. And did you think discounts of 72 percent 12 below published AWPs were within reason?</p> <p>13 MR. GOBENA: Object to the form.</p> <p>14 THE WITNESS: I think we pushed the states 15 to negotiate more aggressively the lower prices and 16 gave them as much information as we could. And we 17 also -- you know, they obviously had rebates that 18 were impacted below this. So yeah, but I mean, the 19 reality is it was my direct responsibility to fix 20 Medicare. It was not my direct responsibility to fix 21 56 different Medicaid programs.</p> <p>22 BY MR. DALY:</p>

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<p>1 Q. And to do so -- well, I mean, I take it      2 that fixing 50 state Medicaid programs would be, you      3 know, versions of trying to fix Medicare times 50.      4 Is that fair?</p> <p>5 A. Yes.</p> <p>6 Q. Because each state would have its own      7 political issues, for example, correct?</p> <p>8 MR. GOBENA: Objection to the form.</p> <p>9 THE WITNESS: Yes. Medicaid is 54      10 territories, 55 different programs that are all      11 complex and all different payment rates and different      12 politics and makes Medicare reform look simple.</p> <p>13 BY MR. DALY:</p> <p>14 Q. And for example, you would have, you know,      15 providers within each state, this time including      16 pharmacies, for example, that would be complaining to      17 state governments if reimbursement levels attempted      18 to be reduced, be reduced, is that true?</p> <p>19 MR. GOBENA: Objection. Form.</p> <p>20 THE WITNESS: Yes. Every state had      21 different pharmacy politics with the providers and      22 what the dispensing fees were and what the</p>	<p>1 increasingly some did.      2 And I authorized the number multi-state      3 purchasing groups which were controversial for states      4 to go ahead and use private PBMs to lower their cost.      5 So it was a concern. For me it was more direct and      6 immediate concern for the Medicare program, which I      7 was directly responsible for. But when states asked      8 me what to do on Medicaid drug pricing, my general      9 advice, which a lot of them did, was to hire a PBM to      10 go out, put them at risk, and drive prices down,      11 which a number of them did.</p> <p>12 BY MR. DALY:</p> <p>13 Q. In your testimony in 2003, you testified      14 that Medicaid has actually become a larger program      15 than Medicare. Do you recall that testimony?</p> <p>16 A. Yes.</p> <p>17 Q. And so why do you say that you didn't have      18 direct responsibility for trying to reduce the      19 federal government's Medicaid payments?</p> <p>20 MR. GOBENA: Objection to the form.</p> <p>21 Mischaracterizes the witness's testimony. You can      22 answer.</p>
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<p>1 acquisition costs were. Yes.</p> <p>2 BY MR. DALY:</p> <p>3 Q. But it was your view, it was CMS's view      4 that if a state wanted to pay to reimburse pharmacies      5 at AWP minus, say, 10 percent, for example, even      6 though the actual acquisition cost of the drug might      7 be AWP minus 72 percent, you did not find that to be      8 unreasonable?</p> <p>9 MR. GOBENA: Objection to the form. This      10 witness is not here as a 30(b)(6) testifying about      11 CMS's views.</p> <p>12 BY MR. DALY:</p> <p>13 Q. Go ahead.</p> <p>14 MR. GOBENA: You can answer.</p> <p>15 THE WITNESS: My personal view was that it      16 was -- was it unreasonable? Yes. I mean, I spent a      17 lot of time complaining to states about trying to      18 make sure that they paid the lower cost for drugs,      19 and some did. And I pushed on a lot of states to      20 hire third party PBMs which a lot of them did, to buy      21 their drugs and lower their acquisition costs and      22 come up with a market-based pricing, which</p>	<p>1 THE WITNESS: I did have responsibility      2 for Medicaid. The federal government runs and      3 manages Medicare day-to-day. And when you had a      4 situation like you did for Medicare, I felt it was      5 probably next to prescription drug reform, which was      6 my number one priority going back in the government.      7 And number two was probably fixing AWP, because it      8 was a big fiscal and management and policy problem      9 for the agency.</p> <p>10 So I spent a lot of time trying to fix it.      11 On Medicaid, I had equal interest but the single      12 biggest Medicaid policy fiscal issue that we had was      13 if -- was the states scamming reimbursement matches      14 which I mentioned earlier, which was a multibillion      15 dollar problem, state by state, with the states      16 because they had a fiscal partnership between the      17 federal and state governments. The single biggest      18 policy problem there that I spent most of my time on      19 was to trying to prevent the states from putting up      20 air to match federal, and drawdown federal dollars      21 without putting out state dollars.</p> <p>22 Once we got to the point where we're</p>

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<p>1 that's -- I realize no time is good for you for this,      2 but we'd certainly work with you on your schedule to      3 find the best possible time to continue.</p> <p>4 MR. HAAS: I object strenuously to the use      5 of the transcript without having the opportunity to      6 cross-examine or redirect on behalf of my client.      7 There has been a number of comments made, testimony      8 made with respect to Johnson &amp; Johnson and its      9 products. And clarification is needed. And absent      10 that opportunity, I strenuously object to his      11 testimony and will proceed accordingly.</p> <p>12 BY MR. DALY:</p> <p>13 Q. What's an FUL?</p> <p>14 A. Federal upper payment limit.</p> <p>15 Q. And do you have a working understanding of      16 when it is that an FUL is supposed to be created for      17 a drug?</p> <p>18 A. I did three years ago. I'm not sure I can      19 remember exactly how it's -- how it works, but it's      20 essentially an upper payment limit for usually I      21 believe a multisource generic drug. But I can't      22 remember exactly what the rule is, but it used to be</p>	<p>1 Q. Right. And that that's something that CMS      2 was going to do?</p> <p>3 A. Yes.</p> <p>4 MR. GOBENA: Object to the form.</p> <p>5 THE WITNESS: Yes. CMS had that      6 regulation in place and I think they put out a new      7 one this year as a matter of fact.</p> <p>8 BY MR. DALY:</p> <p>9 Q. And do you know why -- or do you know      10 whether FULs were ever created for any of the drugs      11 that the DOJ has sued Abbott for in this litigation?</p> <p>12 A. I don't know. I assume so, but I don't      13 know. I mean, Vancomycin is a generic, I think. So      14 I assume there was an FUL, but I'm not familiar, I'm      15 not specifically familiar with it.</p> <p>16 Q. And sodium chloride is certainly a      17 generic, right?</p> <p>18 A. Yes. So I assume there is an FUL for all      19 of them.</p> <p>20 Q. Well, let me represent to you that there      21 are not, and then my question would be, do you know      22 why?</p>
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<p>1 --</p> <p>2 Q. Three or more?</p> <p>3 A. Yes. I think it was 250 percent or I      4 can't -- 250 percent or whatever the, I can't      5 remember the rule.</p> <p>6 Q. Do you remember what triggered the      7 creation of FULs in terms of if there are three or      8 more different drugs that are functional equivalents      9 that CMS would then prepare or create an FUL for      10 that, those three drugs?</p> <p>11 MR. GOBENA: Object to the form.</p> <p>12 BY MR. DALY:</p> <p>13 Q. Is that -- I'm just trying to see if that      14 jogs your memory?</p> <p>15 A. I just can't remember precisely how it      16 works. It's been three years.</p> <p>17 Q. Well, you remember that it was something      18 to do with if there are a number of drugs that can be      19 full substitutes for each other within a basically      20 the same drug?</p> <p>21 A. Yes. It's the maximum amount CMS will pay      22 for any of them.</p>	<p>1 MR. GOBENA: Object to the form.</p> <p>2 THE WITNESS: No. I don't. I think      3 before you get off that, I should clarify, I assume      4 it's because they are infused drugs, and the FULs are      5 generally pharmacy dispensed drugs for the most part.      6 I assume that's the reason.</p> <p>7 BY MR. DALY:</p> <p>8 Q. Okay. But you don't know?</p> <p>9 A. I don't know.</p> <p>10 (Exhibit Abbott 196 was      11 marked for identification.)</p> <p>12 BY MR. DALY:</p> <p>13 Q. Mr. Scully, I've handed you what we've      14 marked as Exhibit Abbott 196 which is an August 10,      15 2001 memorandum to you from Michael Mangano, who is      16 the principal deputy inspector general attaching an      17 OIG report from August 2001. And did you receive a      18 copy of this memorandum from Mr. Mangano?</p> <p>19 A. I don't recall, but I'm certain I did.</p> <p>20 Q. In the -- this document is entitled      21 Medicaid pharmacy actual acquisition cost of brand      22 name prescription drug products, is that correct?</p>

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1 sure I probably agreed with it. 2 Q. Well, do you agree with it now? 3 A. Yes. 4 Q. If you just flip to the very end of this 5 and maybe this will refresh your recollection, maybe 6 it won't, but the last couple of pages are a letter 7 from you to Janet Rehnquist. Do you see that? 8 A. Yes. 9 Q. And is that your signature up by the from 10 box? 11 A. It looks like it might be. 12 Q. Okay. So it would appear that you got 13 this and sent Ms. Rehnquist back a response? 14 A. Yes. But since I probably saw 4 or 500 15 documents a night before I went home sometimes, 16 whether or not I read it or not is another question. 17 But I'm sure I agree with the conclusion in there. 18 Q. Well, in a lot of cases, you relied on 19 your staff to prepare letters and review things and 20 work on responsive letters with you, correct? 21 A. Yes. 22 Q. And when you wrote a letter such as this,	1 states for drugs. And states increasingly did that. 2 Q. On the -- if you go back to the letter 3 from Ms. Rehnquist to you on the second page, do you 4 see she indicates that in the second -- in the first 5 full paragraph, last sentence, "unlike brand name 6 drugs where reimbursement is predominantly based on a 7 discounted AWP, reimbursement of generic drugs can be 8 limited by a federal upper limit amounts that are 9 established by CMS." Do you see that? 10 A. Yes. 11 Q. And was it your understanding that CMS was 12 charged with responsibility to create FULs for drugs 13 that met the requirements of an FUL? 14 MR. GOBENA: Object to the form. 15 THE WITNESS: I believe so. Yeah, Larry 16 Reed who I mentioned earlier today is the guy who did 17 that. 18 BY MR. DALY: 19 Q. And is it your experience that setting an 20 FUL for a drug that qualified to be given an FUL had 21 the effect of reducing reimbursement for that drug? 22 MR. GOBENA: Object to the form.
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1 to Miss Rehnquist, you were speaking on behalf of 2 CMS, correct? 3 A. Yes. 4 Q. In the last part of the response, in the 5 very last page of the document, you indicate that it 6 was your intent to follow up with the states and 7 strongly encourage them to review their estimates of 8 acquisition costs, do you see that? 9 A. Yes. 10 Q. And to follow up with them to ensure that 11 their actions take those findings into account. Do 12 you see that? 13 A. Yes. 14 Q. Did CMS in fact do that? 15 A. I'm sure we did. I talked to many states 16 about paying more reasonably for drugs. As I said 17 earlier, my general approach was not to have states 18 pay fee for service amounts for drugs, because in 19 many cases, the political pressure was not easy to 20 get that done. It was always more effective in my 21 opinion to hire a third party at-risk PBM, because 22 they are much more likely to get lower prices for	1 THE WITNESS: You know, I do not -- it was 2 never one of my primary policy issues to get involved 3 in the process for setting FULs, so my general 4 recollection is it was pretty wide range and there 5 wasn't usually a big reduction as a result of FULs. 6 BY MR. DALY: 7 Q. Mr. Scully, I'm going to hand you what has 8 been marked previously as Exhibit Abbott 108, which 9 is an OIG report relating to omission of drugs from 10 the federal upper limit list in 2001. And I would 11 direct your attention to the last few pages which 12 contained the CMS response signed by you, is that 13 correct? 14 A. Yes. That is my signature. Yep. 15 Q. I wanted to direct your attention to 16 Romanette number i of the report, which is the third 17 page in. Under the executive summary. And I want to 18 direct your attention to the second paragraph, which 19 talks about the requirements for when CMS is to 20 prepare an FUL for a given group of drugs. And I 21 just ask you to read that to yourself, and then ask 22 you if that's consistent with your understanding of

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<p>1 the requirements for a creation of an FUL.      2 MR. GOBENA: Object to the form.      3 BY MR. DALY:      4 Q. Have you had a chance to look at that      5 paragraph?      6 A. Yes.      7 Q. Is that consistent with your understanding      8 of when CMS was to create an FUL?      9 MR. GOBENA: Object to the form.      10 THE WITNESS: Yes. I forgot the 150      11 percent number, yeah, earlier.      12 BY MR. DALY:      13 Q. Okay. And then what you just referenced      14 in your earlier testimony, you said maybe it was 250      15 percent?      16 A. CMS came out with a new rule this year      17 that it was 250 percent of a different calculation      18 that I can't remember exactly how it worked.      19 Q. And in terms of when you were at CMS, the      20 rule was 150 percent of the published price for the      21 least costly therapeutically equivalent product plus      22 a reasonable dispensing fee, right?</p>	<p>1 THE WITNESS: No. I'm not. I was      2 minimally involved in this process as you can tell.      3 MR. DALY: Let's do this one here, Exhibit      4 Abbott 095.      5 BY MR. DALY:      6 Q. Let me hand you what's been previously      7 marked as Exhibit Abbott 095. And this is a      8 September 2001 OIG report relating generally to the      9 -- what we've called the DOJAWPs. And I wanted to      10 direct your attention to the CMS comments at the end,      11 they are the last couple of pages. And we talked      12 about Ruben King-Shaw. That's somebody -- he was      13 your deputy administrator?      14 A. Yes.      15 Q. And he obviously prepared the response      16 here?      17 A. Yes.      18 Q. And did you have any discussions with him      19 about the technical correction that he made in the      20 last paragraph?      21 A. Last paragraph of his response?      22 Q. Yes.</p>
<p>1 A. I believe that's right.      2 Q. And again, did you -- you don't know why      3 the drugs that DOJ has sued Abbott on in this case      4 were not FULed is that correct?      5 MR. GOBENA: Objection. Asked and      6 answered.      7 THE WITNESS: I don't know. I'm guessing      8 because they were infused drugs, they were not in the      9 calculations somehow.      10 BY MR. DALY:      11 Q. Is there some exception to the FUL      12 calculation for infused drugs?      13 A. I don't know. I don't remember.      14 Generally, in Medicare, there is a differential      15 between infused drugs and, you know, outpatient drugs      16 delivered to pharmacy. And I assume maybe there is      17 some differentiation in Medicaid I wasn't aware of.      18 Q. But you're not aware of any exception from      19 the requirement that CMS create an FUL for a drug      20 that qualifies that's based on it being an infused      21 drug, are you?      22 MR. GOBENA: Objection to the form.</p>	<p>1 A. On this page or where? Oh, I see, "we      2 appreciate the effort."      3 Q. The very last page of the response, page 2      4 of his letter. I'll read it.      5 A. I see it. No. I don't recollect having a      6 discussion with him.      7 Q. Well, do you see that he says that the      8 original report stated that the inflated AWPs have      9 caused Medicare to overpay for these products. Do      10 you see that?      11 A. Yes.      12 Q. And he asked that the overpayment language      13 be removed. Do you see that?      14 A. I'm sorry. What have I missed? I thought      15 he was correcting it.      16 Q. It's the second page. It's this paragraph      17 here. Had you looked at that paragraph when I asked      18 you those other questions, Mr. Scully?      19 A. No. The earlier question?      20 Q. Right.      21 A. No. I didn't see this, but Ruben had just      22 come from being two weeks before the Secretary of</p>
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<p>1 Health in Florida, so I'm assuming since I don't      2 discuss it with him, he probably didn't like the --      3 probably, he always felt this way, didn't like the IG      4 taking shots at states, so he probably asked to      5 remove it.</p> <p>6 But we didn't discuss it, but it's very      7 Rubenesque. I would guess that was the intent of the      8 tone is he just didn't like the IG suggesting states      9 are overpaying, so much more than any other factual      10 basis. Much more than any other policy based factor.      11 I think he probably just didn't like the comments      12 about accusing the states of overpaying.</p> <p>13 Q. Because CMS had approved their plans to      14 pay whatever it was that they were paying, right?</p> <p>15 MR. GOBENA: Object to the form.</p> <p>16 THE WITNESS: Because it implies the      17 states are making errors or overpaying, and Ruben had      18 just been a state Medicaid administrator and was      19 probably as aggressive as anybody in the country      20 about trying to reduce drug prices. So I'm sure he      21 resented that. Probably took it out for that result      22 -- for that reason.</p>	<p>1 to be all day or half a day or anything like that,      2 but I'm not going to be able to finish it tonight, so      3 I'm thinking that at 6 o'clock, I know a lot of      4 people have to go. I know I have to catch a plane,      5 so you know, subject to your prior comments, I think      6 this might be a good time to conclude.</p> <p>7 THE WITNESS: Is there any reason why      8 other people can't stay longer, I mean, given the      9 issue of -- I mean, it would be convenient for      10 everybody's time, but it's extremely inconvenient for      11 my time to come back for any more than I have to      12 obviously. And if you have to catch a plane, is      13 there any reason why other people can't ask      14 questions, with the other counsel, co-counsel here?</p> <p>15 MR. GOBENA: Why don't we go off the      16 record.</p> <p>17 MR. DALY: Off the record.</p> <p>18 THE VIDEOGRAPHER: The time is 6:04 p.m.      19 Off the record with videotape number 7.</p> <p>20 (Recess.)</p> <p>21 THE VIDEOGRAPHER: The time is 6:08 p.m.      22 We are continuing with tape number seven.</p>
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<p>1 BY MR. DALY:</p> <p>2 Q. He resented the implication that the      3 states were doing anything wrong, is that what you're      4 saying?</p> <p>5 A. The states were not effectively trying to      6 negotiate the lowest prices, at least in his state,      7 which is the way he thought, so I'm guessing this was      8 a much more personal thing than a policy      9 consideration at CMS.</p> <p>10 Q. Although when he wrote this letter, he was      11 speaking on behalf of --</p> <p>12 A. He was.</p> <p>13 Q. CMS, right?</p> <p>14 A. I'm just saying that he had been -- I'm      15 guessing from our previous letters with Mike      16 McMullen, he had been deputy administrator for about      17 two weeks, and I know from dealing with him as my      18 deputy for two and half years, he had strong feelings      19 about what the states -- states rights to run their      20 own programs.</p> <p>21 MR. DALY: Well, I've got probably three      22 or four more areas to cover with you. It's not going</p>	<p>1 BY MR. DALY:</p> <p>2 Q. Mr. Scully, I just wanted to follow up on      3 something you gave in one of your last few answers      4 which was when we were talking about average      5 discounts below AWP that pharmacies for example and      6 others were able to acquire drugs under the Medicaid      7 program. We were talking about the averages and you      8 said that there were a lot of high volume, low cost      9 drugs which might skew that average. Do you recall      10 that testimony?</p> <p>11 A. Yes.</p> <p>12 Q. And those are high volume, low cost drugs,      13 that's where you would expect the larger spreads to      14 be?</p> <p>15 A. I just generally recollect that was the      16 case. Some of the higher, the higher spreads were in      17 low cost drugs.</p> <p>18 Q. Okay. And the low cost drugs would      19 include sodium chloride, dextrose and water?</p> <p>20 MR. GOBENA: Object to the form.</p> <p>21 THE WITNESS: I'd have to look. I don't      22 remember those particular. I remember ipratropium</p>

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<p>1 bromide and Albuterol being the two kind of poster 2 children for that.</p> <p>3 BY MR. DALY:</p> <p>4 Q. Do you recall sodium chloride, dextrose 5 and water being low cost drugs under the Medicaid 6 program?</p> <p>7 MR. GOBENA: Object to the form.</p> <p>8 THE WITNESS: I don't. I'd have to look 9 at the pricing. I assume they are, but I'm --</p> <p>10 MR. DALY: All right. I just wanted to 11 get that. And did you have anything you wanted to 12 say after your meeting?</p> <p>13 MR. GOBENA: Yes. As Mr. Scully has 14 indicated, he is prepared to proceed as long as 15 possible tonight to get as much of the questioning 16 done. So what I want to do is go around the room and 17 ask each one of the defense counsel here representing 18 various drug companies whether or not they are 19 willing to continue going tonight, even though I 20 understand Mr. Daly has to catch a plane, Mr. Cook is 21 here. He could ask questions for Abbott if Abbott 22 has additional areas of inquiry. But I'll let all of</p>	<p>1 take until you actually get into it. There's been a 2 lot of, frankly, in our opinion, repetitive, 3 redundant questioning going on today. But you know, 4 there might be a disagreement about that.</p> <p>5 But leaving that aside, we are willing to 6 continue. We are not talking about going all night 7 long until tomorrow morning. We can go for hopefully 8 a few more hours at least, try and get some of the 9 questioning in from Dey's counsel, from Roxane's 10 counsel, you know, and try and get as much of it done 11 as possible.</p> <p>12 MR. ESCOBAR: Let me ask you this. Why is 13 it that you're saying that? Is there no day in the 14 next six months where we can all reconvene and do 15 this in an orderly way?</p> <p>16 MR. GOBENA: I'm not saying that, I'm just 17 asking whether or not --</p> <p>18 MR. ESCOBAR: Excuse me, are you saying 19 that there is no day --</p> <p>20 MR. GOBENA: Let me answer your question, 21 Mr. Escobar. I'm saying -- what I'm asking right now 22 is a different question. Are you willing to ask some</p>
<p>1 you speak for yourselves to state on the record 2 whether you're willing to stay further tonight, so we 3 can continue and complete as much of his testimony as 4 possible.</p> <p>5 MR. DALY: I mean, you can ask anybody 6 whatever you want to ask them. I just have two 7 things to say. One, there was no indication from you 8 that this would be a one-day deposition. Number two, 9 the court reporter has informed us they are not going 10 to stay here all night. They have been at this now 11 for however many hours it's been, and it's just not 12 reasonable that folks, you know, have to continue and 13 work 14 hours straight, or 15 or 16 or 18, or however 14 --</p> <p>15 THE WITNESS: Well, that's a 16 misrepresentation by my counsel, then, because I 17 very, very, very clearly and very directly told them 18 that I want to start as early today as I could and go 19 -- excuse me, and go as long as I possibly could 20 today.</p> <p>21 MR. GOBENA: It's no misrepresentation. 22 Look, we don't know how long a deposition is going to</p>	<p>1 questions now. I'm not saying there is no day or 2 anything. I'm not taking a position on that.</p> <p>3 MR. HAAS: But it's a moot point. We 4 don't have a court reporter. I mean, correct me if 5 I'm wrong, but there is no notice that this was going 6 later than the standard number of hours today. 7 People have their plans based upon that. We don't 8 have a court reporter, and I don't understand the 9 point.</p> <p>10 MR. GOBENA: What are the standard number 11 of hours. In our case, it says 14 --</p> <p>12 MR. HAAS: There is nothing about going 14 13 hours a day.</p> <p>14 MR. GOBENA: It doesn't say anything about 15 going 8 hours or not.</p> <p>16 MR. HAAS: In this case, have you gone 14 17 hours?</p> <p>18 MR. GOBENA: No one's talking about going 19 14 --</p> <p>20 MR. HAAS: I'm asking you. There is none.</p> <p>21 MR. BREEN: Let me just interject here. 22 Let's not get all hot under the collar. The bottom</p>

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UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF MASSACHUSETTS

IN RE: PHARMACEUTICAL INDUSTRY ) MDL NO. 1456  
AVERAGE WHOLESALE PRICE )  
LITIGATION ) CIVIL ACTION:  
 ) 01-CV-12257-PBS  
 ) Judge Patti B. Saris  
 ) Magistrate Judge  
 ) Marianne B. Bowler

THIS DOCUMENT RELATES TO

U.S. ex rel. Ven-A-Care of the  
Florida Keys, Inc., v.  
Abbott Laboratories, Inc., et al.  
No. 06-CV-11337-PBS

(Caption continues on next page.)

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VIDEOTAPED DEPOSITION OF

CODY WIBERG

Taken March 14, 2008

Commencing at 9:13 a.m.

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<p>1 A. Oh, yes, yes, indeed.</p> <p>2 Q. We'll get to that in detail later, but could</p> <p>3 you describe that work at a high level of</p> <p>4 generality?</p> <p>5 A. Well, basically, again, under federal law,</p> <p>6 states are allowed to set reimbursement rates for</p> <p>7 pharmaceuticals. And so since we managed the fee</p> <p>8 for service pharmacy program, we obviously had a</p> <p>9 lot to say about what those rates should be.</p> <p>10 Q. And you -- did you work with the legislature</p> <p>11 and the legislature's passing of laws that related</p> <p>12 to dispensing fees and reimbursement formula?</p> <p>13 A. That's correct. Unlike some other states,</p> <p>14 where Medicaid reimbursement rates can be set by</p> <p>15 the agency, by rule, in Minnesota, unless things</p> <p>16 have changed, and at least in the pharmacy area,</p> <p>17 and I think in most areas, the legislature</p> <p>18 establishes the rates.</p> <p>19 MR. COOK: Mr. Wiberg, let me hand you</p> <p>20 what we have marked in previous depositions as</p> <p>21 Exhibit Abbott 19.</p> <p>22 THE WITNESS: It's a copy of the</p>	<p>1 Q. And could you take a look at those drugs and</p> <p>2 tell me if you -- if you recognize those drugs?</p> <p>3 A. The top one appears -- the top two appear to</p> <p>4 be cut off. But otherwise, yes.</p> <p>5 Q. And does this appear to be a -- to describe</p> <p>6 them at a -- at a higher level of generality?</p> <p>7 Sodium saline solution, dextrose solution,</p> <p>8 vancomycin, and water.</p> <p>9 A. Uh-huh.</p> <p>10 Q. What kinds of drugs are-- are those?</p> <p>11 A. At a high level, I think what you want to</p> <p>12 know is they're injectable drugs. They're drugs</p> <p>13 that are commonly used in -- in IV therapy.</p> <p>14 Q. These wouldn't be the types of pills, for</p> <p>15 example, that you were dispensing when you were --</p> <p>16 a community -- community pharmacist, right?</p> <p>17 A. That's correct.</p> <p>18 Q. And as we go along, and happy to have you --</p> <p>19 you keep a copy of that. When I refer to the</p> <p>20 subject drugs in the federal case, I'm referring to</p> <p>21 the drugs that are here on Exhibit 1. These are</p> <p>22 the ones that are the subject of the government's</p>
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<p>1 complaint in this case.</p> <p>2 MR. BLACK: I just want to see which</p> <p>3 case.</p> <p>4 MR. COOK: It is the complaint that was</p> <p>5 originally filed or the complaint and intervention</p> <p>6 filed by the Department of Justice. And it's</p> <p>7 Abbott.</p> <p>8 MR. BLACK: Intervention?</p> <p>9 MR. COOK: It's the complaint and</p> <p>10 intervention. And for the record -- it was filed</p> <p>11 in March of 2006.</p> <p>12 BY MR. COOK:</p> <p>13 Q. Just as an initial matter, Mr. Wiberg, have</p> <p>14 you ever seen this document before, to your</p> <p>15 knowledge?</p> <p>16 A. I'm not sure. Unless you've -- folks sent it</p> <p>17 to me, then I don't believe that I have, no.</p> <p>18 Q. Okay. Well, actually what I'd like to turn</p> <p>19 your attention to is the very last two pages of the</p> <p>20 document that are labeled Exhibit 1. And it's a</p> <p>21 list of drugs.</p> <p>22 A. Uh-huh.</p>	<p>1 lawsuit against -- against Abbott.</p> <p>2 A. Uh-huh.</p> <p>3 Q. Do you know what the allegations are that</p> <p>4 have been made by the Department of Justice in this</p> <p>5 case against Abbott?</p> <p>6 A. In this particular case, no. Because I have</p> <p>7 not read this document.</p> <p>8 Q. Are you familiar generally with the AWP</p> <p>9 litigation that's been going on for so many years</p> <p>10 in the country?</p> <p>11 A. Yes, I have.</p> <p>12 MR. FAUCI: Objection, form.</p> <p>13 BY MR. COOK:</p> <p>14 Q. What is your understanding of what that AWP</p> <p>15 litigation relates to?</p> <p>16 MR. FAUCI: Objection to form.</p> <p>17 A. I think my understanding is that the basic</p> <p>18 allegation is that pharmaceutical manufacturers</p> <p>19 either falsely reported information or withheld</p> <p>20 information about the true cost of pharmaceuticals</p> <p>21 that they, in fact, inflated average wholesale</p> <p>22 prices in an effort to win market share for their</p>

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1 cost of dispensing prescription medications to 2 Medicaid recipients." Do you see that? 3 A. Yes, I do. 4 Q. And that would be consistent with your 5 general understanding of what Myers and Stauffer 6 was doing for various state Medicaid programs, 7 right? 8 A. Correct. I know that's one of their -- the 9 things that they -- they did. I don't know what 10 else they might have done.	1 customers walking in from the street. They don't 2 fill prescriptions for oral medications, typically. 3 Instead, they fill injectable drugs, basically. 4 Normally, they actually have to prepare or compound 5 these drugs. And these are dispensed to patients 6 who are receiving intravenous therapy at home. 7 Well over a decade ago, maybe close to two 8 decades ago now, as just a general part of 9 cost-saving efforts, some of the -- the procedures 10 that used to be done, first in doctors' offices or 11 hospitals, then in outpatient clinics or -- or 12 outpatient areas of hospitals, were gradually 13 shifted to the home. So patients who were thought 14 to be not so critically ill that they needed to be 15 in a home were -- would get treat -- or excuse me, 16 in a hospital, would get treatment at a home. 17 Q. Now, this move from hospital to home for 18 these infusion therapies, first as a subjective 19 matter, is it your experience that patients would 20 rather be at home than in a hospital? 21 A. I think that depends on the patient. I -- I 22 never worked in home infusion pharmacy. So --
11 Q. And then if you look down under Summary of 12 Findings in this 2002 report, at the first bullet 13 point there, it's in bold, on the very first page 14 of the Executive Summary. "Myers and Stauffer 15 indicates what it finds as the statewide median 16 cost of dispensing weighted by Medicaid volume to 17 be, right"? 18 A. Correct. 19 Q. And in here it shows it to be \$5.95, right? 20 A. Correct. 21 Q. And that is almost mathematically in the 22 middle of what you were saying earlier the	
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1 Minnesota Pharmacy Association was pegging as -- as 2 its cost of dispensing, right? 3 A. Yes. As I recall, they -- that's the -- the 4 general range they were talking about. They may 5 have even had a specific amount. But somewhere in 6 that range is what I recall them claiming it to be. 7 Q. If I could turn your attention to page 23, 8 and on pages 23 through 25, what I'd like to do is 9 turn your attention to aspects of this report that 10 looked specifically at the cost of dispensing for 11 I.V. and infusion pharmacies as opposed to retail 12 pharmacies. Do you understand that distinction? 13 A. Yes. 14 Q. Before looking at this, could you tell me, 15 what's your understanding of the difference between 16 an I.V. or infusion pharmacy and a -- and a retail 17 community pharmacy? 18 A. Well, a -- sometimes there is no distinction, 19 actually. Some pharmacies do both. But there are 20 specialty pharmacies that are referred to as home 21 health care pharmacies, or home infusion pharmacies 22 that are closed-door pharmacies. They don't have	1 Q. From the Medicaid point of view -- 2 A. Yep. 3 Q. -- as a pure question of economics, however, 4 did you have an understanding of whether it was 5 cheaper or generally more expensive for Medicaid to 6 pay for infusion in the home as opposed to 7 admission into the hospital? 8 A. To tell you the truth, if you look at the 9 totality of costs, no. I -- I wasn't -- I really 10 don't know for sure. One would assume that it's 11 cheaper to pay for the nondrug costs outside of the 12 ho -- you know, outside of the hospital. That the 13 hospitalization would be more expensive than 14 treating someone in the home. That would be the 15 assumption I would make, although I did not do 16 hospital rates, so I don't know. 17 Q. Well, do you know if within Medicaid there 18 was any policy considerations of preferring out of 19 hospital treatment because to the program as a 20 whole, it would save money over in-patient 21 admissions? Or have other policy benefits, such as 22 lack of infection, comfort to the patient?

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<p style="text-align: right;">Page 82</p> <p>1 A. I would assume that's the case, but I can't      2 say that for certainty, because, again, I didn't      3 work on -- on the policy issues involving      4 hospitalization versus home care when it went to      5 those costs.</p> <p>6 Q. So to the extent there was someone within      7 either the legislature or the agency that was      8 looking to -- to try to move patients from -- into      9 hospitals or out of hospitals or into home care or      10 out of home care, that would have been some other      11 aspect of the agency?</p> <p>12 A. Correct.</p> <p>13 Q. Okay. Could you describe for me the -- well,      14 let me back up. When one dispenses a drug in a      15 retail pharmacy, it's typically pills, right?</p> <p>16 A. It's oral medications, typically with a few      17 injectables.</p> <p>18 Q. All right. So -- and so it might include,      19 like, the liquids that I would give my kids with      20 the Tylenol suspension.</p> <p>21 A. Liquids, capsules, suppositories, gels,      22 ointments, emulsions, creams.</p>	<p style="text-align: right;">Page 84</p> <p>1 paid. The label gets printed, along with a      2 receipt. If it is a cap -- excuse me, tablets,      3 capsules, solid dosage forms, oral dosage forms,      4 somebody counts it out, somebody labels it.</p> <p>5 The pharmacist in -- in this state, and I'm      6 sure all states then, by law, has to certify the      7 accuracy of the prescription, particularly if      8 somebody else entered the information. And once      9 the -- and that involves comparing the actual      10 written prescription with what's printed on the      11 label and what's in the bottle to make sure that      12 everything is correct.</p> <p>13 Once that's done, the medication is bagged,      14 the receipt's put onto it. And, again, if      15 pharmacists are following the law in this state,      16 when the patient comes into the pharmacy for new      17 prescriptions, the pharmacist is supposed to go out      18 and counsel them on their medication. That's --      19 that a typical process.</p> <p>20 The only significant difference between that      21 and the other sort of things out there is,      22 obviously, for prepackaged creams and ointments</p>
<p style="text-align: right;">Page 83</p> <p>1 Q. What generally goes into dispensing those      2 types of oral medications?</p> <p>3 A. The typical process would be that a -- for a      4 new prescription, let's say, the patient presents      5 at the pharmacy with a prescription -- well, back      6 in those days. More and more, actually, the      7 prescription is being electronically transmitted to      8 -- from the clinic to the pharmacy.</p> <p>9 But back in those days still, most of it was      10 the patient would walk into the pharmacy with a      11 prescription from a doctor, someone at the pharmacy      12 would enter the data. That could be a pharmacist,      13 it could be a pharmacy technician. Once the data      14 was entered into the system, if the person was on      15 some sort of insurance or in managed care, and      16 therefore had a pharmacy benefit, a claim would be      17 transmitted to -- either directly to the payer, in      18 the case of our program, or more commonly, to      19 something called a Pharmacy Benefit Manager. That      20 Pharmacy Benefit Manager would do the sort of      21 things I talked about before in terms of editing      22 the claim. If everything was fine, the claim gets</p>	<p style="text-align: right;">Page 85</p> <p>1 that come that way from the manufacturers, bottles      2 of eyedrops, there's no counting. The label just      3 goes directly on the container.</p> <p>4 Q. And when we talk about the -- you know, the      5 -- \$5.50 to \$6.50 or \$5.95 cost of dispensing the      6 product to the pharmacy, are you referring to that      7 process, plus whatever overhead is involved?</p> <p>8 A. Correct.</p> <p>9 Q. All right. I know that you never worked in      10 an infusion or I.V. pharmacy, but do you have an      11 understanding of how the dispensing process is      12 different for an I.V. or infusion pharmacy?</p> <p>13 A. I would have a basic understanding, primarily      14 because you can't graduate from pharmacy school      15 without having done a hospital pharmacy internship.      16 And I did work in the hospital pharmacy, and I was      17 involved in compounding I.V. preparations as part      18 of my training as a pharmacist.</p> <p>19 Q. And did that process of compounding and      20 preparing infusion or I.V. products to be      21 dispensed, was it typically more involved, or less      22 involved than dispensing oral medications?</p>

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<p>1 A. It's more involved.</p> <p>2 Q. All right. Could you describe for me at a</p> <p>3 high level of generality how it's more involved, or</p> <p>4 what more is involved in that process?</p> <p>5 A. Well, for example, drugs that are meant to be</p> <p>6 administered by I.V. infusion, in some cases, can</p> <p>7 be prepared directly by a manufacturer. There are</p> <p>8 certain drugs that, because of the way that they're</p> <p>9 handled, or because of preservatives or whatever,</p> <p>10 are stable. And then they can actually be</p> <p>11 dispensed pretty much directly, maybe with some</p> <p>12 minor reconstitution; adding something like normal</p> <p>13 saline into the drug. Other drugs are much more</p> <p>14 complex. So, for example, a -- what's known as a</p> <p>15 TPN or Total Parental Nutrition Therapy. These are</p> <p>16 very large volume I.V. bags in which multiple</p> <p>17 different ingredients are mixed together.</p> <p>18 Basically a source of protein, a source of sugar,</p> <p>19 multiple vitamins, different vitamins, like what</p> <p>20 are called electrolytes. So you could have many</p> <p>21 different things that go into one bag.</p> <p>22 Now, what I'm not going to be able to do is</p>	<p>1 pharmacy technician do it. Pharmacists, in some</p> <p>2 places, probably directly do this themselves. But</p> <p>3 actually, pharmacy technicians probably do most of</p> <p>4 the actual mixing and compounding, and then the</p> <p>5 pharmacist is certifying for accuracy.</p> <p>6 Q. Okay. Well, if I could turn your attention</p> <p>7 to page 23 of Exhibit 21, this is the August 2002</p> <p>8 Myers and Stauffer report for Texas.</p> <p>9 MR. COOK: And, again, just for the</p> <p>10 record, so somebody watching it or reading the</p> <p>11 transcript knows what we're talking about, I'm</p> <p>12 going to read just the second to the last paragraph</p> <p>13 there. And then ask you questions about it.</p> <p>14 A. Uh-huh.</p> <p>15 BY MR. COOK:</p> <p>16 Q. Quote, The two most significant</p> <p>17 characteristics that affected pharmacy dispensing</p> <p>18 cost, were the provision of intravenous or home</p> <p>19 infusion solutions, and the provision of</p> <p>20 pharmaceutical compounding services. Our analysis</p> <p>21 revealed significantly higher cost of dispensing</p> <p>22 associated with the 53 pharmacies in the sample</p>
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<p>1 tell you the advances in the last 25 years.</p> <p>2 Because when I did this, we did everything by hand.</p> <p>3 My understanding now is that the home I.V. infusion</p> <p>4 pharmacies and hospital pharmacies that do this for</p> <p>5 in-patients have automated devices that essentially</p> <p>6 you -- my understanding, having not actually seen</p> <p>7 these, is that you load the manufactured</p> <p>8 containers, and you do the calculations, and the</p> <p>9 device does the mixing.</p> <p>10 Q. From a business point of view for the</p> <p>11 pharmacy, presumably the cost of dispensing would</p> <p>12 also include, I guess, the cost of that sort of</p> <p>13 machine, right?</p> <p>14 A. Yes.</p> <p>15 Q. And it would be -- I guess a typical business</p> <p>16 question to decide whether it's cheaper to pay for</p> <p>17 a pharmacist to do it by hand, or cheaper to go out</p> <p>18 and buy the machine for whatever it costs and have</p> <p>19 it done more efficiently, and perhaps more</p> <p>20 accurately.</p> <p>21 A. To tell you the truth, the business</p> <p>22 consideration is probably whether or not to have a</p>	<p>1 that provided these services, close quote.</p> <p>2 Given your experience as the manager of the</p> <p>3 Minnesota Medicaid Pharmacy Program, and as a</p> <p>4 pharmacist, does that conclusion by Myers and</p> <p>5 Stauffer surprise you?</p> <p>6 A. No.</p> <p>7 Q. In fact, you would expect that I.V. and home</p> <p>8 infusion provision and compounding services would</p> <p>9 increase the cost of dispensing to a pharmacy,</p> <p>10 right?</p> <p>11 A. Yes.</p> <p>12 Q. And then if you turn to page 24, the next</p> <p>13 page over, there are three bullet points there</p> <p>14 where Myers and Stauffer, would you agree with me,</p> <p>15 lays out the reasons that pharmacists with whom</p> <p>16 they spoke gave for these costs being higher for a</p> <p>17 home infusion or I.V. pharmacy. Do you see that?</p> <p>18 A. I do.</p> <p>19 Q. And would you agree with me that summarizing</p> <p>20 these, Myers and Stauffer was told by these</p> <p>21 pharmacists, according to the report, that the cost</p> <p>22 of special equipment for mixing and storing the</p>

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<p>1 I.V. solutions was one factor, correct?</p> <p>2 A. The costs of special equipment? That would</p> <p>3 make sense, yes.</p> <p>4 Q. And then second is they're higher direct</p> <p>5 labor costs, because of mixing and manual</p> <p>6 activities to fill the I.V. -- I.V. prescriptions?</p> <p>7 A. That would make sense as well.</p> <p>8 Q. And that's the second factor named in the</p> <p>9 report, right?</p> <p>10 A. Yes.</p> <p>11 Q. And then the third was that -- and I'll just</p> <p>12 read this. Quote, A pharmacy may mix and deliver</p> <p>13 many dispensings of a daily intravenous solution</p> <p>14 from a single prescription, thus incurring</p> <p>15 additional costs spread over a smaller number of</p> <p>16 prescriptions, close quote.</p> <p>17 Does that factor also make sense to you?</p> <p>18 A. It does.</p> <p>19 Q. Okay. And then if we go down to table 3.3,</p> <p>20 which is just a little bit farther down on the page</p> <p>21 on page 24?</p> <p>22 A. Uh-huh.</p>	<p>1 Q. Now, compounded prescriptions as opposed to</p> <p>2 I.V. prescriptions, what do you understand the</p> <p>3 difference between those two types of prescriptions</p> <p>4 to be?</p> <p>5 A. Well, many I.V. prescriptions are, in fact,</p> <p>6 compounded prescriptions, so I.V. prescriptions are</p> <p>7 often a subset of the general term, compounded</p> <p>8 prescriptions. I believe what they're probably</p> <p>9 referring to here would be -- well, they actually</p> <p>10 state it. They're referring to prescriptions that</p> <p>11 are compounded, but that aren't for I.V. use. So</p> <p>12 that could be anything, again, from ointments,</p> <p>13 creams, oral solutions. Some pharmacies even do</p> <p>14 capsules. Some that specialize in compounding</p> <p>15 pharmacy will even press out tablets. So there's a</p> <p>16 -- suppositories. There is a whole wide range of</p> <p>17 different types of products that can be compounded.</p> <p>18 Q. All right. The magnitude of -- of these</p> <p>19 conclusions that Myers and Stauffer reached, are</p> <p>20 they consistent with your understandings when you</p> <p>21 were the manager of the Minnesota Pharmacy Program</p> <p>22 for the Medicaid?</p>
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<p>1 Q. -- do you see that Myers and Stauffer reports</p> <p>2 the unweighted mean cost of dispensing</p> <p>3 prescriptions for three different types of</p> <p>4 pharmacies.</p> <p>5 A. I see that, yes.</p> <p>6 Q. And then down at the bottom, they first refer</p> <p>7 to pharmacies that do not dispense intravenous or</p> <p>8 compounded prescriptions, right?</p> <p>9 A. Correct.</p> <p>10 Q. And Myers and Stauffers reports -- you</p> <p>11 obviously don't know if it's correct, but Myers and</p> <p>12 Stauffers reports an unweighted mean cost of \$6.96,</p> <p>13 right?</p> <p>14 A. That's what they report here, yep.</p> <p>15 Q. Right. And then the next up, they report</p> <p>16 pharmacies dispensing compounded prescriptions but</p> <p>17 not intravenous prescriptions as \$9.13, right?</p> <p>18 A. That's correct.</p> <p>19 Q. And then they report the unweighted mean cost</p> <p>20 for pharmacies dispensing intravenous and home</p> <p>21 infusion prescriptions is \$41.75, right?</p> <p>22 A. That's correct.</p>	<p>1 A. I'm not quite sure what you mean by that.</p> <p>2 Q. Sure. Do these findings surprise you at all?</p> <p>3 A. Well, I don't think I'd speak to the exact</p> <p>4 amounts here. Because again, we never did a cost</p> <p>5 of dispensing study. If the question is framed</p> <p>6 more, does it surprise me that -- that I.V. home</p> <p>7 infusion pharmacies have a higher cost of</p> <p>8 dispensing, and that compound -- that pharmacies</p> <p>9 that specialize in compounding other preparations</p> <p>10 have a somewhat lower cost of dispensing, then at</p> <p>11 the lowest costs of dispensing are pharmacies that</p> <p>12 don't do a substantial amount of I.V. or compounded</p> <p>13 prescriptions. That hierarchy doesn't -- does not</p> <p>14 surprise me.</p> <p>15 Q. But the exact numbers for -- you know \$41.75</p> <p>16 or \$6.96, you can't say whether it's right or</p> <p>17 wrong, because you didn't have the data, right?</p> <p>18 A. We -- we didn't do that sort of study.</p> <p>19 Q. The last column on that chart shows standard</p> <p>20 deviation.</p> <p>21 A. Uh-huh.</p> <p>22 Q. Now, I'm not a statistician, but do you have</p>

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<p>1 an understanding of what standard deviation refers 2 to?</p> <p>3 A. The only thing I can surmise -- I'm not a 4 statis -- statistician either. Well, no, it 5 wouldn't make any sense with the first one. No, I 6 really don't. I don't know what they mean.</p> <p>7 Q. As a general matter, do you understand 8 standard deviation to refer to the range of --</p> <p>9 A. Yes.</p> <p>10 Q. -- of data within that set?</p> <p>11 A. That's correct.</p> <p>12 Q. And would it also not surprise you that 13 pharmacies dispensing I.V. and home infusion 14 prescriptions would have the widest range of costs, 15 as opposed to retail pharmacies, which have a more 16 narrow range of costs?</p> <p>17 A. Well, given that they have a higher cost to 18 begin with, I would expect to see a larger 19 deviation, yes. There's just less room to deviate 20 from \$6.96, that they have reported here, compared 21 to \$41.75. What I don't understand is the \$72.59. 22 Is that supposed to be a range around \$41.75? I</p>	<p>1 Q. If you turn to the next page, at the very 2 first paragraph, the second sentence, and I'll just 3 read it for the record. "Based on our cost 4 findings, it must be concluded that the costs 5 incurred to dispense intravenous or compounded 6 prescriptions are not representative of the costs 7 incurred by a general pharmacy." Close quote. Is 8 that also consistent with your experience?</p> <p>9 A. Yes.</p> <p>10 Q. And then if we turn to the -- to the 11 footnote, you see footnote 11 on page 25? And I'll 12 just read that for the record. Quote, Although 13 typical dispensing fees reimburse less than the 14 dispensing costs of intravenous pharmacies, they're 15 generally able to break even, based on the margin 16 allowed on ingredient cost reimbursement.</p> <p>17 Compounding pharmacies predominantly market their 18 services to self-pay customers, and do not solicit 19 Medicaid reimbursement for most compounding 20 services, close quote.</p> <p>21 Focusing your attention on the first sentence 22 of that footnote, relating to I.V. pharmacies. Is</p>
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<p>1 don't know.</p> <p>2 Q. All right. And would it surprise you that 3 I.V. and home infusion pharmacies would have a -- a 4 wider range of the types of things that one does as 5 opposed to another does, as opposed to a community 6 pharmacy, where most of them do about the same 7 thing?</p> <p>8 A. Yeah, that's -- that's a possibility. I 9 guess, you know, it doesn't surprise me that there 10 might be, again, a wider range of costs for -- for 11 I.V. pharmacies, I guess. It would depend on 12 exactly what -- what they're doing. There may be 13 specialty -- or maybe you would call them 14 subspecialty I.V. infusion pharmacies that deal 15 with very critically ill people that have drugs 16 that are more difficult to handle and to store and 17 that sort of thing.</p> <p>18 Q. And, of course, from a policy perspective at 19 Medicaid, that sort of range presents a difficult 20 policy question if you're trying to set a single 21 price that fits everybody, right?</p> <p>22 A. It would.</p>	<p>1 that consistent with your experience as the direct 2 -- as the Manager of Pharmacy Program at Minnesota 3 Medicaid?</p> <p>4 A. Actually, no.</p> <p>5 Q. How so?</p> <p>6 A. Well, one of the things I didn't mention 7 earlier, because, you know, again, I've been out of 8 this for a while. And I was thinking more in terms 9 of -- of general -- our general reimbursement rate. 10 We did not -- the rate that I used before for 11 dispensing fees, \$3.65, is not what we paid I.V. 12 infusion pharmacies.</p> <p>13 Q. What did you pay I.V. infusion pharmacies?</p> <p>14 A. We paid them substantially more. And I 15 inherited this. It was actually something I -- I 16 personally thought we may have been paying them too 17 much. And actually, tried to have it changed. 18 And rather than it being changed, it ended up being 19 embedded in law. It had been something that one of 20 my predecessors, I don't know how far back, had put 21 into place. When I became aware of this, I 22 actually asked the -- the person who was doing the</p>

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<p style="text-align: right;">Page 98</p> <p>1 pricing for compounded I.V. drugs where this      2 reimbursement rate came from, and where it was in      3 statute. She was a retired pharmacist that      4 manually did these. And she said, well, that's the      5 way we've always done it. And I went actually to      6 get this -- tried to get this in law, so that we      7 would have a statutory basis for making these      8 payments. And my suggestion was to reduce that      9 rate. But the legislature decided not to do that.</p> <p>10 Q. Do you know what the rate was?</p> <p>11 A. I am going to probably not get it exactly      12 right. But it really depended on what was being      13 compounded. We had one rate for what you might      14 call standard I.V. drugs, which would include a      15 drug like vancomycin, a relatively simple      16 antibiotic. We had another rate for drugs that      17 were used for chemotherapy in cancer patients      18 because of the hazards associated with that and the      19 extra difficulty in compounding those. We had the      20 highest rate for the TPN solutions, those drugs      21 that I mentioned before -- or excuse me, those      22 nutritional solutions I mentioned before that are</p>	<p style="text-align: right;">Page 100</p> <p>1 e- r- r- e- a- u- l- t-.</p> <p>2 Q. Do you recall what Miss Perreault told you      3 was the rationale for having a different dispensing      4 fee for these pharmacies?</p> <p>5 A. Well, the rationale was basically because      6 there are increased costs for compounding I.V.      7 solutions. I might add, in addition, we -- in      8 addition to the dispensing fee, my understanding      9 was that we paid separately for certain special      10 containers that -- and I'm not an expert in I.V.      11 home infusion pharmacy, but there -- in addition to      12 the -- the sort of plastic bags you might see on a      13 television medical show, there are special      14 containers in which these preparations can be      15 prepared. And some of those are much more      16 expensive than just a simple plastic or vinyl bag.      17 And so we paid extra for those, in addition. I      18 don't know exactly how much we paid for those.</p> <p>19 Q. And, as I understand it, you proposed that      20 that be changed.</p> <p>21 A. I had discussions with my management about      22 that, basically saying -- the basic thrust of it</p>
<p style="text-align: right;">Page 99</p> <p>1 in large-volume bags, and where many things have to      2 be mixed in there. I believe, and I may be wrong,      3 but I believe we paid \$8 per bag for the simpler      4 products. We paid \$13 per bag for chemotherapy      5 products. We paid 30 -- something in the 30s, 33      6 is sticking in my mind here, for TPN products that      7 were one liter or less, and 40 -- per bag. And we      8 paid \$44 per bag for TPN solutions that were      9 greater than one liter.</p> <p>10 Q. And you learned this how long after you      11 became the Manager of this Pharmacy Program?</p> <p>12 A. I don't know exactly. See, first when I      13 worked for the Department, I was actually the Drug      14 Utilization Review Coordinator. I'm pretty sure I      15 didn't know then, because I wasn't involved in --      16 in the pricing issues at that point. So I don't      17 know exactly -- I think probably sometime within      18 the first year that I took over as the manager.</p> <p>19 Q. And who was the person that explained to you      20 this differential dispensing fee for these      21 services?</p> <p>22 A. Her first name is Marie, and -- Perreault, P-</p>	<p style="text-align: right;">Page 101</p> <p>1 is, look, we really need this in statute. I don't      2 feel comfortable making these payments when, you      3 know -- at one point, I think the department did --      4 I think that's where these came from. I never was      5 able to track this down, other than what Marie told      6 me. But I think at one point the Department had      7 the authority -- authority itself to set rates, and      8 it didn't have to go through the legislature. At      9 some point, the legislature stopped allowing the      10 agency to do that. And I think what happened is,      11 when the rates were established in statute, nobody      12 looked at this. That's what I think happened. And      13 so Marie kept pricing them out at that level. And      14 so most of my discussion with management was, this      15 really needs to be part of our -- the governor's      16 proposal this year, whatever year that was, because      17 we really ought to have something on the books that      18 authorizes us to make these payments.</p> <p>19 Q. And what was the proposal?</p> <p>20 A. Well, the proposal was just to -- to put it      21 into statute, is what senior management decided to      22 do.</p>

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<p>1 Q. But you said that you had proposed going to      2 the -- the regular --      3 A. No.      4 Q. Okay.      5 A. I -- I actually never got to the point where      6 I made a specific proposal to management. It was      7 more general discussions about, I think we're      8 paying too much. And --      9 Q. Now, why did you think you were paying too      10 much?      11 A. Well, again, we're paying at that rate, just      12 for the simplest things, not \$8 per dispensing, as      13 we're talking about here. We're talking about \$8      14 per bag. Which gets at -- I think one of the      15 comments that you referred to earlier. Where there      16 might be multiple dispensings that might drive up      17 their costs.      18 What I actually wanted to do at that point was      19 -- was to try to convince management we needed to      20 look more closely at it. That's why I really      21 hadn't gotten to a specific amount, because we      22 needed to look at whether that was realistic. I</p>	<p>1 remembered her name.      2 A. She -- she left the department not too long      3 afterwards. But we did have some discussions, and      4 I think one of the reasons senior management      5 decided, yeah, we better get this in statute right      6 now, until we figure out what to do, because you're      7 right, this really ought to be in law if we're      8 paying this out. But one of the reasons I think      9 they didn't want to at that point cut reimbursement      10 rate is, we had talked -- this other woman who had      11 policy for home health care and myself, had started      12 to have discussions about bundling. In other      13 words, we would pay a per diem to the home      14 healthcare companies, and out of that per diem,      15 they would have to pay for nursing services, the      16 pharmacy services, and any other ancillary      17 services, as a bundled package. And that kept      18 getting pushed to the back burner, first because      19 that woman left and her replacement had to be      20 trained. And then by the -- you know, the budget      21 problems we had 2002 and 2003 hit, and there were,      22 quite frankly, much easier ways to save money than</p>
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<p>1 just had the sense, and maybe I would have been      2 proved wrong, if we had studied it. But I had the      3 sense that \$8 per bag, and then especially with the      4 TPNs, \$44, \$33 per bag was a lot. And plus, we did      5 know, you know, even back then, that there was a      6 spread between AWP and what the pharmacies were      7 covering. So my thought was that if we have -- we      8 don't know exactly what it is, because there is no      9 pricing transparency, but the assumption is,      10 they're -- they're making money on the ingredient      11 side, and now we're turning around and we're paying      12 them dispensing fees per bag, and in some cases,      13 we're paying for extra, you know, special      14 packaging. And I -- I had a general sense that      15 that might be too much.      16 One of the reasons I believe -- remember I      17 said before, I was not involved in -- I was      18 involved in the pharmacy area. Someone else      19 managed the home health services. And I did have      20 some discussions with the woman, and I -- I will      21 not be able to remember her name, because --      22 Q. You knew my next question was whether you</p>	<p>1 -- than working on that, which was a very difficult      2 issue to try to figure out.      3 Q. And so to bring it back to Exhibit 21, in the      4 Myers and Stauffer report, where they were speaking      5 to Texas I.V. pharmacists --      6 A. Right.      7 Q. -- where the Texas I.V. pharmacists may have      8 told Myers and Stauffer, I'm not making a      9 dispensing fee but I'm making more profit on the      10 ingredient cost, in Minnesota you found out that      11 the I.V. pharmacists were making it on both ends.      12 A. That was my impression.      13 Q. Okay.      14 A. Yep, indeed.      15 Q. What was the ultimate legislative resolution      16 of this?      17 A. As I mentioned before, they simply took the      18 rates we were paying, and put them in statute.      19 Q. And the I.V. pharmacists continued to be paid      20 based upon the regular formula for ingredient cost,      21 correct?      22 A. That is correct.</p>

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<p>1 Q. So that would be AWP minus some percent.      2 A. Yeah, which varied during the time I was      3 there.</p> <p>4 Q. Did you have an understanding that that      5 formula, AWP minus whether it's 9 percent or 12      6 percent or some other amount, resulted in a higher      7 profit for I.V. pharmacists than it did for      8 community pharmacists?</p> <p>9 A. At the time I was working there, no, I      10 didn't. Because, again -- well, for a couple of      11 reasons, I think. First of all, as I mentioned      12 before, we had no authority to ask people what they      13 were actually paying for drugs. We had no idea      14 whether or not home infusion pharmacies might be      15 getting discounts from manufacturers or from      16 wholesalers. So, no. I really don't know if they      17 were -- if they were liable to make more of a      18 profit than a community pharmacy would, based on      19 that formula.</p> <p>20 Q. Okay. To the extent that the I.V. pharmacies      21 were using more generics than branded products --      22 for example, sodium saline solution is probably</p>	<p>1 policies. But, anyway, the -- our primary focus was      2 probably more on -- not on -- on infusion therapy.      3 The primary reason being, remember, I managed the      4 Fee for Service Pharmacy Program. And in      5 Minnesota, the 200 or slightly over 200,000 people      6 that were in that program, the ones that were left      7 in Fee for Service were primarily disabled people.      8 And of those, the -- by far, the predominant sort      9 of disability was mental illness. So the amount of      10 money that we paid on I.V. infusion drugs compared      11 to what we paid on antipsychotics was -- I don't      12 want to use the term minimal, because we paid a lot      13 of money for those, as well, although I don't      14 remember the exact amount. But we certainly paid      15 collectively a lot more for other drugs. And so      16 when you are managing a program, and you have to      17 produce savings like we had to do in 2001, 2002 --      18 well, actually, right through today, I think      19 they're still doing it. You -- you -- you target      20 those drugs that -- where most of the money gets      21 spent. So what we looked at -- again, were mainly      22 the -- I would say the oral medications. And we --</p>
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<p>1 about as generic as you can get, right?      2 A. Right.</p> <p>3 Q. Would it be your understanding that the      4 spreads as a percentage would be higher for those      5 I.V. pharmacies than for a community pharmacy      6 dispensing branded pharmaceuticals.</p> <p>7 A. Assuming that we -- assuming that we didn't      8 put a MAC on the product. And I don't recall if we      9 put MACs on -- on saline or not, to tell you the      10 truth. But if -- had we put a MAC on the product,      11 then presumably, the amount that they were making      12 relative to what they were paying would not have --      13 would have -- yeah, would have been -- the spread      14 would have been reduced.</p> <p>15 Q. How did you decide which drugs to MAC?      16 A. Well --</p> <p>17 Q. If I can turn that word into a verb.      18 A. Yes. No, we use it as a verb. In fact,      19 since we -- it's a state MAC. We sometimes talk      20 about SMACing.</p> <p>21 Anyway, the -- and certainly, pharmacies      22 accused us of SMACing them with our reimbursement</p>	<p>1 exactly how we did that depended on when I was      2 there. When I started there, we had very simple      3 language that essentially allowed us to establish a      4 Maximum Allowable Cost on any drug that had at      5 least one generic product available. My      6 predecessor, in order to -- he was asked to come up      7 with a 1 percent savings. So his proposal had been      8 to do more retrospective drug utilization review.      9 And as he put it, to re-establish the MAC program,      10 although one had been in existence. I think he      11 wanted to reinvigorate it, you might say. His idea      12 was that in order to do that, you really had to      13 have something in statute. So you had to have some      14 sort of legislative proposal, and quite frankly, by      15 the time certain individuals that were representing      16 lobbyists that were representing brand name      17 manufacturers got through with the legislative      18 process, we ended up with less authority to      19 establish MACs.</p> <p>20 So at that -- so from -- I think that was done      21 in '99. So from then until I could get that      22 reversed in 2002, we could not establish a MAC for</p>

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<p>1 any drug that was already on the federal upper      2 limit list. And there -- and CMS took a long time      3 after generics became available to put those      4 generics on the federal upper limit list. So that's      5 one thing we couldn't do. We also had to have the      6 brand name, plus at least two generics.</p> <p>7 After 2002, when I got that language reversed,      8 we went -- we again had the authority to establish      9 a MAC on anything that had at least one generic.      10 And so that's what we did. As drugs went off      11 patent and generics were introduced, as soon as      12 those drugs were out in the market, we would MAC      13 the products.</p> <p>14 Q. We'll come to it in more detail in a little      15 bit, but you refer to the legislature and influence      16 from affected constituencies affecting eventually      17 legislation, right?</p> <p>18 A. Yes.</p> <p>19 Q. Was it a political policy decision in      20 Minnesota how much it was that Minnesota Medicaid      21 was paying for prescription drugs?</p> <p>22 A. A political -- what's a political policy</p>	<p>1 (A brief recess was held.)</p> <p>2 VIDEOGRAPHER: We are now back on the      3 record. This is the continuing videotaped      4 deposition of Cody Wiberg, taken on March 14th,      5 2008. Time now is approximately 11:26 a.m.</p> <p>6 BY MR. COOK:</p> <p>7 Q. Mr. Wiberg, if I could turn your attention      8 back to Exhibit 19, it's the -- the complaint with      9 the list of subject drugs on it.</p> <p>10 A. Okay.</p> <p>11 Q. In what circumstances -- we started to touch      12 on this a minute ago with the managed care versus      13 the fee for service. But in what circumstances      14 would the fee for service portion of Minnesota      15 Medicaid pay for these products?</p> <p>16 A. Well, directly -- there would be two ways.      17 It would be direct and indirect. To the extent      18 that the Medicaid program paid for anyone who was      19 hospitalized as an inpatient, that would be one      20 way, which I had nothing to do with, because that's      21 all essentially a capitated arrangement based on      22 what are called DRGs.</p>
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<p>1 decision?</p> <p>2 Q. You're right.</p> <p>3 MR. BLACK: Good question.</p> <p>4 BY MR. COOK:</p> <p>5 Q. I can ask that better. The amount that      6 Minnesota Medicaid was paying for drugs at the end      7 of the day was the result of the political process.      8 Is that a fair summary?</p> <p>9 MR. FAUCI: Objection.</p> <p>10 A. Well, it was set by the legislature. The      11 legislature consists of politicians. That's the      12 way it worked in Minnesota. It was not a      13 regulatory or bureaucratic decision. The rates for      14 all Medicaid payments were set by the legislature.</p> <p>15 Q. Is this a good time for a short break --</p> <p>16 A. Yeah.</p> <p>17 Q. -- since we're coming to the end of another      18 tape?</p> <p>19 A. Sure.</p> <p>20 MR. COOK: We can go off the record.</p> <p>21 VIDEOGRAPHER: We are going off the video      22 record at 11:19 a.m.</p>	<p>1 In terms of the outpatient setting, we would      2 pay for these -- probably primarily to home I.V.      3 infusion pharmacies, or at least they would be the      4 pharmacies that would be most likely to dispense      5 these sort of products.</p> <p>6 As I believe I mentioned earlier on, there are      7 some pharmacies that are a hybrid. I mean, there      8 are some pharmacies, particularly in outstate      9 Minnesota, where the -- the larger home I.V.      10 infusion pharmacies may not have a presence, or      11 where the pharmacist thought that they could      12 compete locally because of the local reputation, or      13 whatever reason. There's a combination. They run a      14 community pharmacy, and they also have facilities      15 to do home I.V. infusion. But my -- my guess would      16 be, and it is a guess, but -- because I didn't look      17 at these specific products to see who exactly --      18 which pharmacies exactly we paid for, but it would      19 make more sense that we paid for more of these for      20 home I.V. infusion pharmacies.</p> <p>21 Q. Would there also be circumstances in which      22 those particular products would be paid in a</p>

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<p>1 physician-administered setting?</p> <p>2 A. Oh, yes. Indeed.</p> <p>3 Q. Starting first with the hospital setting.</p> <p>4 Again, just to exclude it, you mentioned DRGs,</p> <p>5 diagnosis-related groups?</p> <p>6 A. Right.</p> <p>7 Q. Do I understand that correctly to be a single</p> <p>8 payment that a hospital would receive, based upon</p> <p>9 the diagnosis of the patient?</p> <p>10 A. That's my general understanding. Again, I</p> <p>11 was not an expert in that, but that's my general</p> <p>12 understanding, is they get essentially a per diem</p> <p>13 amount based on the diagnosis of the patient.</p> <p>14 Q. And so if Mr. Black here went to the hospital</p> <p>15 because had he had had a heart attack, and he got a</p> <p>16 bag of saline as part of that, the hospital</p> <p>17 wouldn't be paid anymore or separately because he</p> <p>18 got one bag of saline or two or three, right?</p> <p>19 A. That's my understanding.</p> <p>20 Q. All right. Now, the I.V. pharmacy we've</p> <p>21 talked about already, right --</p> <p>22 A. Uh-huh.</p>	<p>1 Q. And then the final context was being</p> <p>2 administered by a physician. Could you explain</p> <p>3 that method of paying for products like this?</p> <p>4 A. Yeah, that -- that is different. The -- in</p> <p>5 certain circumstances, at least when I was there,</p> <p>6 and this possibly may have changed since I was</p> <p>7 there. But when I was there, we did pay</p> <p>8 physicians, outpatient surgical centers, facilities</p> <p>9 like that, if they were administering drug -- and</p> <p>10 emergency rooms. If they were administering drugs</p> <p>11 in an outpatient setting, they could bill</p> <p>12 separately for the drugs. When I got there, and,</p> <p>13 again, I'm not quite sure how this was established.</p> <p>14 It was before I was there. We were paying flat</p> <p>15 AWP. And, again, we were looking for cost-cutting</p> <p>16 measures. So what I proposed at the time, or --</p> <p>17 well, there were two different proposals over the</p> <p>18 years. The first proposal I had -- I'm guessing</p> <p>19 2001, 2002, was to go to AWP minus 5 percent. That</p> <p>20 was selected, because at that time, I believe</p> <p>21 that's what Medicare was paying. Now, my mistake</p> <p>22 in crafting that bit of -- of legislation was</p>
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<p>1 Q. -- is a closed pharmacy that would prepare it</p> <p>2 and dispense it to whether it's a home health</p> <p>3 agency or nursing home or some other entity that</p> <p>4 would administer the drug. Do I have that correct?</p> <p>5 A. Basically. My understanding is some of the</p> <p>6 home health care businesses really own both</p> <p>7 components. They -- they own the nursing component</p> <p>8 and the pharmacy component. So it may all be</p> <p>9 within one corporate umbrella, I guess.</p> <p>10 Q. And the same might be true, say, for a</p> <p>11 nursing home.</p> <p>12 A. Possibly. Possibly. It's a possibility. I</p> <p>13 think it's more common -- well, these days, there</p> <p>14 are -- in Minnesota, there are several large</p> <p>15 nursing home pharmacy chains. I don't know if</p> <p>16 they're owned by corporations that also own nursing</p> <p>17 homes or not. But there are several large chains</p> <p>18 that have -- national chains that have a presence</p> <p>19 in Minnesota that -- that do a lot of nursing home</p> <p>20 business in this state. How much of the I.V.</p> <p>21 infusion business they do for nursing homes, I'm</p> <p>22 not quite sure about that.</p>	<p>1 actually specifying AWP minus 5 percent. What I</p> <p>2 should have done then, and what we later did do, is</p> <p>3 reference the federal rate. So right now, the --</p> <p>4 unless it's changed since I've been there, right</p> <p>5 now, the language basically says, Medicaid will pay</p> <p>6 for the outpatient administration of drugs at</p> <p>7 whatever rate Medicare pays for.</p> <p>8 Q. And you understand that now to be average</p> <p>9 sales price plus 6 percent, plus some sort of a</p> <p>10 professional fee.</p> <p>11 A. Now that you mention it, that -- that is the</p> <p>12 formula. I -- I wouldn't have been able to recall</p> <p>13 that, but yes, I do recall ASP plus 6 plus a fee.</p> <p>14 Q. Now, when one of these products, one of the</p> <p>15 subject drugs was dispensed by a pharmacy, what</p> <p>16 sort of a form would Minnesota Medicaid receive in</p> <p>17 order to pay the claim?</p> <p>18 A. When it's dispensed by a pharmacy?</p> <p>19 Q. Yes, sir.</p> <p>20 A. A pharmacy claims -- well, that evolved, too,</p> <p>21 at the time I was there.</p> <p>22 When I first started, I think most of those</p>

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<p>1 claims came in on paper. And it was a pharmacy      2 claim, basically. We -- we did our own in-house      3 billing. We did not hire a fiscal intermediary or      4 whatever to process our claims. When the pharmacy      5 world in general moved to a new claims processing      6 standard that's called NCPDP 5.1, NCPDP 5.1 has --      7 has a provision in it so that pharmacies submitting      8 a claim can indicate that it's a compounded claim,      9 and there are multiple lines where -- NDC or the      10 drug code for each drug can be listed. And on each      11 of those lines, you can list the NDC, you can list      12 the quantity you used if you're compounding, and      13 then our system was able then to look line by line,      14 and calculate, yes, we'll pay for this product,      15 because it's -- it's made by a rebating      16 manufacturer. No, we won't pay for the next      17 ingredient. Yes, we'll pay for the final three.      18 And --      19 Q. Or it's MACed.      20 A. Or it's MACed -- well, at whatever rate we      21 paid. Either at the normal rate or a MAC rate,      22 whatever. It calculated the ingredient</p>	<p>1 Once that happened, we also covered a much      2 broader range of compounded products.      3 Q. And these pharmacy claims forms, they're the      4 forms that would have the usual and customary      5 charge, and the description of the product      6 dispensed by NDC, National Drug Code, correct?      7 A. Correct.      8 Q. When a physician administered a product such      9 as those listed on Exhibit 19, what sort of form      10 would -- would he send in?      11 A. My understanding would be what -- when I      12 started, was called a HCFA 1500, now called a CMS      13 1500, so -- since HCFA is now called CMS.      14 Q. What sort of information would be included on      15 that form about the drug that was administered?      16 A. What would be there are what are known as      17 HCPCS codes.      18 Q. What are HCPCS codes?      19 MR. COOK: And for the court reporter,      20 that's all caps, H-C-P-C-S.      21 A. You know what the acronym stands for, I don't      22 know anymore. But HCPCS codes are codes that</p>
<p>1 reimbursement, line by line, including -- you know,      2 there were some lines that would be rejected. If      3 we paid for everything, if we paid for every drug      4 in every line, it would add those all up. It was      5 sophisticated enough to know how many bags were      6 submitted, so it could properly do the 8, the 13 or      7 those other fees I mentioned. And it would simply      8 pay the claim. If we rejected one line, we would      9 pend or stop the claim. The pharmacy, in essence,      10 would get a message back that would say, this is      11 what we're willing to pay. If that was some      12 ingredient, like normal saline, that was relatively      13 cheap in a small quantity, like maybe they only      14 added 100 milliliters, they might actually decide      15 -- cheap for them to purchase. They might actually      16 decide, we're fine with the rest of the      17 reimbursement. And then they could send a code      18 back that said, yeah, pay us. If it was a more      19 expensive ingredient, they might say, wait, well,      20 we're gonna lose money, and then they would not      21 send a claim back and it would become a noncovered      22 service. So that's how it evolved over time.</p>	<p>1 physicians, outpatient facilities, a wide variety      2 of nonpharmacy providers, use in their billing.      3 There are a huge number of HCPCS codes. I mean,      4 the HCPCS manual is at least that big (indicating.)      5 The ones in pharmacy that we were most concerned      6 about were called J codes, because they started      7 with J. There were some other drugs that weren't J      8 codes, but most of them were J codes. J codes, or      9 HCPC codes in general, at that time were not --      10 they're not tied to a specific product. What they      11 are -- as an example, using your list of drugs      12 here, they're made -- and I'm not sure if this is      13 true, because I haven't looked at a HCPCS manual in      14 two-and-a-half years. But there may be a code, you      15 know, J something or other, J 1251 or whatever,      16 that says, for 100 milliliters of dextrose      17 solution, for that quantity, the HCPCS code is for      18 that quality, 100 milliliters dextrose Liposyn      19 solution. And so that would be a HCPCS code.      20 Q. Now for the NDC claim on the pharmacy side,      21 you could go look up the published AWP for that NDC      22 at First DataBank, right?</p>

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<p style="text-align: center;">Page 122</p> <p>1 A. We -- we could look it up. That's not how we 2 did it, but we could look it up. 3 Q. How did you do it? 4 A. When I started there, we received -- was it 5 monthly or biweekly? I think it was monthly. We 6 received monthly data tapes from First DataBank. 7 Q. So the computer would go look it up. 8 A. The computer would go look it up. 9 Q. Okay. With the ND -- with the J codes, with 10 the HCPCS codes, how would the program go about 11 determining what the payment amount would be for a 12 particular J code? 13 A. Well, there were actually -- although we were 14 involved in the policy setting, there were -- there 15 was another unit, again, with -- within DHS, that 16 did rate settings, that were responsible for 17 actually entering the -- the rates data. 18 Presumably, what they were doing, what they should 19 have been doing, in the case of pharmaceuticals 20 when I started, is they would have been trying to 21 determine what AWP was. I think, actually, as I 22 recall what they were doing, though, is they --</p>	<p style="text-align: center;">Page 124</p> <p>1 discussions among my counterparts at meetings we'd 2 attend about having physicians, to the extent 3 possible, bill by NDC code. For the primary 4 reason, as I mentioned before, one of the things we 5 did is we collected rebates. And prior to the time 6 that I started, maybe even for the first year or so 7 -- oh, definitely in our state for maybe a year or 8 two, or maybe even a little bit more after I 9 started, we weren't collecting rebates for drugs 10 that were administered by physicians and billed by 11 HCFA, or CMS 1500 forms. And my understanding is, 12 prior to becoming involved with the Medicaid, most 13 states didn't do that. Then some states took a 14 closer look at the federal language. And what the 15 federal language talks about is collecting rebates 16 on outpatient drugs. It doesn't say outpatient 17 drugs dispensed by a pharmacy. So some other states 18 first started collecting rebates for those drugs, 19 and that's actually one of the proposals that I 20 came to our legislature with. And we started doing 21 that. And at first, what we had to do is, we had 22 to build what we called a crosswalk, which meant</p>
<p style="text-align: center;">Page 123</p> <p>1 even before it became part of statute, they were 2 looking at what Medicare was paying and trying to 3 figure out what Medicare was paying, and how, since 4 Medicare, I think, was taking AWP minus 5 percent 5 off, I -- I assume they were adding that 5 percent 6 back in, because we were paying a flat AWP. So I 7 think they were relying -- for their data, I think 8 they were relying on -- on Medicare, I think. 9 Q. But a single J code would include drugs from 10 several manufacturers, right? 11 A. It could. Or it could be one to one. 12 Q. Right. For a drug such as sodium saline 13 solution or dextrose, would it be your 14 understanding that a physician would get the same 15 payment, regardless of which manufacturer's -- 16 A. That's correct. 17 Q. -- self solution he used. 18 A. That's correct. At that time. 19 Q. Well, has it since changed? 20 A. I'm not sure if it has changed, but the 21 systems are getting sophisticated enough in -- we 22 had discussions -- actually, they were national</p>	<p style="text-align: center;">Page 125</p> <p>1 that we only collected rebates for those drugs 2 where there was a one-to-one match between the NDC 3 and a HCPCS or J code. 4 Q. That might be a J code that has only one drug 5 in it. 6 A. Correct. 7 Q. So you know that -- 8 A. That had to be from that manufacturer, 9 correct. 10 Q. Got it. 11 A. I think there were other states, and I don't 12 recall if they did it or not. I think there may 13 have been other states that were trying to -- based 14 on claims that they did get, sort of proportionally 15 assign the rebates to the various manufacturers. 16 Minnesota never -- never did that. But that was 17 one of the reasons why Medicaid pharmacy managers, 18 like myself, were very interested in seeing the -- 19 the billing standard change so that physicians, 20 other outpatient facilities, would have to bill by 21 NDC so we could collect the rebates in those 22 products, as well.</p>

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<p style="text-align: right;">Page 138</p> <p>1 copies of Red Book, but actually, we typically      2 would -- we might look to that to make sure that      3 there were still multiple generics available. We      4 might look at that just to look up an NDC number,      5 if we were doing clinical research, and we want the      6 to look up something about the drug or something      7 like that. But we relied on the data we got from      8 First DataBank. This -- this data was      9 automatically loaded into the computer, goes in at      10 the end of the day, runs overnight. And the --      11 what -- that First DataBank does not provide just      12 pricing data. All of the data that's needed to do      13 those clinical pharmacy edits I mentioned comes      14 from them, as well. The drug, drug interactions,      15 that sort of thing. So, again, there -- there was      16 some consideration of doing something like maybe      17 Texas did, but the trade-off in that is, you would      18 have to hire a small Army of people to recreate      19 what First DataBank did.</p> <p>20 Q. Were you aware at the time you were Manager      21 of the -- the Pharmacy Program in Minnesota that      22 manufacturers had reported direct prices that would</p>	<p style="text-align: right;">Page 140</p> <p>1 a large infusion pharmacy?      2 A. Specific knowledge, no. But the assumption      3 would be that there would be volume discounts.      4 Q. And you're familiar with the -- the term,      5 "the commodity," right?      6 A. Uh-huh.      7 Q. Would sodium saline, dextrose, would those --      8 water, would those be products you would consider      9 to be commodities?      10 A. Well, we sure -- we didn't really think of      11 drugs of any sort, if they were approved as drugs,      12 as commodities, per se. That's not the way we      13 looked at them.      14 Q. All right. Certainly closer to a commodity      15 than a branded, patent-protected drug, correct?      16 A. Well, no, I wouldn't -- I wouldn't say that's      17 necessarily correct. I mean, the one time I      18 actually heard them use -- the word "commodity"      19 used, because that's not a word I used in      20 connection with administering the Pharmacy Program.      21 The one time I actually heard someone refer to a      22 drug as a commodity actually came from a brand-name</p>
<p style="text-align: right;">Page 139</p> <p>1 be published in some of these compendia?      2 A. I -- now that you mention the term "direct      3 price," yes.      4 Q. Did you have an understanding of what direct      5 price was?      6 A. To tell you the truth, no.      7 Q. Did you have any understanding that it was      8 similar to the usual and customary rate; the amount      9 that a person with whom you have no contract, no      10 negotiations, a cash purchase for a single unit      11 would pay for that product?      12 MR. BLACK: Objection to form.      13 A. No, not really.      14 BY MR. COOK:      15 Q. Okay.      16 A. It's not a -- it's not a price figure that we      17 used in any of our payment methodologies, so --      18 Q. All right. Did you have any understanding      19 about the difference between what manufacturers      20 were charging for a product such as sodium saline      21 between a single bag of saline sold directly to a      22 customer versus 20,000 units sold to a hospital or</p>	<p style="text-align: right;">Page 141</p> <p>1 manufacturer. It was a manufacturer of one of a      2 group of drugs that are known as proton pump      3 inhibitors, the most famous of which is the little      4 purple pill, Nexium, that's advertised ad nauseam      5 on TV for nausea, among other things. But proton      6 pump inhibitors was the first category of drugs --      7 before we started doing a preferred drug list, it      8 was actually the first category of drugs that      9 showed us the potential for significant savings if      10 we did a preferred drug list. And, I'll admit, we      11 sort of stumbled into it.      12 Q. How did that happen?      13 A. Well, I inherited a prior authorization      14 program from my predecessors that was basically      15 ineffective. The one group of drugs where my      16 predecessors had made an attempt to do prior      17 authorization was failing, and that was with proton      18 pump inhibitors. The Drug Formulary Committee,      19 both before I started there, and for the first year      20 or two after I was there, insisted that physicians      21 be allowed to prescribe a proton pump inhibitor      22 without prior authorization for the first four to</p>

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<p style="text-align: right;">Page 170</p> <p>1 considerations at the time.      2 So if you wanted to make it -- and you would      3 have three choices, basically. You could either      4 make it -- try to make it as close as you could to      5 revenue-neutral. You could try to recoup savings.      6 And therefore, you -- you're going to set the      7 dispensing fee maybe not as high as you would if      8 you were going make it revenue-neutral. Or you      9 could try to actually pay providers more money      10 then, and you would set it a little bit higher.      11 But I basically -- when this came out, and at that      12 conference I mentioned, where -- where Mr. Lup --      13 Mr. Lupinetti and I both were presenters at a      14 conference. We were talking about different      15 issues, and I was not talking about this particular      16 issue, per se. But he was talking about this      17 issue. And I did basically bring up that, you      18 know, you really have to understand how the      19 pharmacy reimbursement system works. You can't --      20 you have to understand that there's two sides of      21 the equation, that the dispensing fees are kept      22 artificially low. That if you just reduce the</p>	<p style="text-align: right;">Page 172</p> <p>1 have to understand that we know, and this is a      2 serious aspect of ain't what paid -- "ain't what's      3 paid." We know AWP, "ain't what's paid." But if we      4 move towards more transparency and we get closer to      5 reimbursing on the ingredient side at what      6 providers actually pay, then we have to look at the      7 dispensing fee side in the case of pharmacies,      8 because we've always kept that below what we think      9 the true cost of dispensing is to make up for the      10 fact that there is some money being made on the      11 ingredient side. So to the extent, again, that you      12 start paying people a dispensing fee or a total      13 reimbursement that does not even get back the cost      14 of the drugs, plus the cost of labor and the      15 computer systems and the lights and all that, you      16 could have providers stop -- you know, start      17 dropping out of Medicaid. And then this creates an      18 access issue for very poor people. So -- yeah.      19 MR. BLACK: Objection, form.      20 Nonresponsive.      21 BY MR. COOK:      22 Q. And so would it be your understanding that if</p>
<p style="text-align: right;">Page 171</p> <p>1 ingredient reimbursement to actual acquisition      2 cost, and don't do anything with the dispensing      3 fee, there's at least the possibility that you're      4 going to have access problems for patients, because      5 pharmacies at that point might drop out of the      6 system.      7 Now, there's an argument that it really      8 wouldn't make much difference, because the very      9 large national pharmacy chains don't necessarily      10 make their money on the prescriptions. They make      11 the money on what you buy in the front end of the      12 store. And if they use pharmacy sales or      13 prescription sales as a loss leader, they'll still      14 sign up for Medicaid.      15 Q. There will be a retail pharmacy, correct?      16 A. Yeah.      17 Q. Not a closed pharmacy like an infusion      18 pharmacy.      19 A. No, no. So there's that argument. But      20 anyway, the argument I made is that you can't --      21 you can't look at one side of the equation. You      22 have to look at both sides of the equation. You</p>	<p style="text-align: right;">Page 173</p> <p>1 we were -- if one were to go to this ideal world in      2 which AWP actually represented acquisition costs,      3 the Medicaid programs would no longer use an AWP      4 minus a percentage.      5 A. To the extent that -- that whatever was used,      6 revamped AWP or an ASP or an AMP, whatever you use      7 as a basis of a cost reimbursement, or -- or excuse      8 me, ingredient reimbursement to the extent that      9 that closely reflected the average actual price the      10 providers paid, then you would -- right. You would      11 no longer be taking percentages off.      12 Q. And, in fact, are you familiar with the      13 manner in which the federal legislation has changed      14 the calculation of federal upper limits to be      15 two-and-a-half times the Average Manufacturer's      16 Price?      17 A. If that's a recent change within the last      18 two-and-a-half years, I wouldn't know.      19 Q. And we've already talked about Medicare      20 paying ASP plus some percentage, correct?      21 A. 6 percent, I believe it is, yep.      22 Q. Once you learned what the actual amounts were</p>

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<p style="text-align: right;">Page 174</p> <p>1 that NAMFCU was distributing as these new AWPs, or      2 First DataBank was distributing, did you yourself      3 take any efforts to go and look at invoice pricing      4 to compare the new AWPs to invoice pricing?      5 A. Yes, I did.      6 Q. Could you tell me about that?      7 A. As I mentioned, at the time I was still      8 moonlighting in the community pharmacy. So the      9 next time I worked a weekend at the community      10 pharmacy, I took my list of 476 drugs and looked at      11 the prices that were at least listed as being the      12 prices that that pharmacy chain paid for the drugs.      13 Again, taking into account that they may have had      14 additional rebates that I was not aware of at all.      15 And just looking at -- at some of those drugs.      16 That's why I became concerned. Because the AWPs,      17 the so-called Medicaid AWPs that were reported did,      18 in fact, in many cases -- not all, but in many      19 cases, were about what this chain pharmacies      20 supposedly was paying for these drugs. That's why      21 I became concerned about them now taking an      22 additional 9 percent off in terms of doing the</p>	<p style="text-align: right;">Page 176</p> <p>1 A. That's probably correct, yeah.      2 Q. And if you look at the end, it indicates,      3 NMPAA-talk.      4 A. Uh-huh.      5 Q. Was that the LISTSERV that you were referring      6 to?      7 A. Yeah, I believe so. Yeah.      8 Q. And it's at ListBot.com.      9 A. Uh-huh. Again, I never paid attention to      10 actually what the LISTSERV was called. I'm not      11 even actually sure who exactly ran it. But yeah.      12 Q. And did you know David Shepherd and Martha      13 McNeill?      14 A. Yes.      15 Q. Who were they?      16 A. David Shepherd is, as the email indicates,      17 worked for Virginia. And my understanding is he      18 was my counterpart in Virginia. Martha McNeill      19 worked for Texas. I don't know if she was actually      20 the Pharmacy Program Manager in charge of all of      21 that, but she certainly was heavily involved. She      22 was a pharmacist that worked for Texas Medicaid on</p>
<p style="text-align: right;">Page 175</p> <p>1 reimbursement.      2 Q. Do you recall receiving any complaints from      3 home infusion or I.V. providers about --      4 A. No.      5 Q. -- these new AWPs?      6 A. Not specifically. There were complaints, as      7 I recall. There were a smattering of complaints,      8 I'd characterize it as, from pharmacy providers.      9 But I don't recall which individual ones they were.      10 Q. Let me hand you what we've marked in a      11 previous deposition as Exhibit 492.      12 If you would give me just a moment.      13 And for the record, Exhibit 492 is an email      14 from David Shepherd in Virginia --      15 A. Uh-huh.      16 Q. -- to Martha McNeill in Texas, dated June 23,      17 2000, forwarding an email from you from the prior      18 day.      19 A. Okay.      20 Q. It looks like it was sent to the National      21 Medicaid Pharmacy Administrators LISTSERV. Do I      22 have that correct?</p>	<p style="text-align: right;">Page 177</p> <p>1 pricing -- on doing the same sort of things that I      2 did.      3 Q. And David Shepherd also was a pharmacist?      4 A. I think so. I'm not quite as sure. But --      5 Q. Did you find Mr. Shepherd and Miss McNeill to      6 be as knowledgeable as you were about the issues      7 relating to drug pricing we've been discussing here      8 today?      9 MR. FAUCI: Objection.      10 MR. BLACK: Objection, form.      11 A. Well, you know, my interaction with them was      12 on a LISTSERV in Massachusetts like this,      13 occasionally seeing them at national meetings, and      14 things like that. In casual conversations, they --      15 they -- I could converse with them. They seemed to      16 understand what I was saying. Their actual level of      17 expertise I don't think I can judge.      18 BY MR. COOK:      19 Q. If you look to the text of your email, you're      20 forwarding the text of an email that you had sent      21 to First DataBank the prior week, correct?      22 A. Well, can I read this?</p>

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1	Q. Oh, please. Take your time. Take your time.	1 your commercial customers. Close quote.
2	A. Yeah, this is from 2000.	2 When you referred to real AWPs, you were
3	Q. Yes, sir.	3 referring to the AWPs that had traditionally been
4	A. I don't remember emails that long. I don't	4 published in First DataBank, correct?
5	remember them eight weeks ago, let alone eight	5 A. Right.
6	years ago. 420 -- 476. I could be wrong. I was	6 Q. And in the next sentence, you indicate that
7	probably more accurate back then.	7 you've discovered that these new AWPs that are
8	Q. In fact, Mr. Wiberg, why don't I give you	8 being reported are at or below actual acquisition
9	Exhibit 380, also --	9 costs, right?
10	A. All right.	10 A. Correct. That's what I put in the -- the
11	Q. -- which is a copy of an email that you	11 email, yes.
12	appear to have sent. And I'll give you time to	12 Q. Right. And you -- and you abbreviate that
13	read both of those at your leisure.	13 with the all caps AAC.
14	A. Okay. I've read this first document.	14 A. Uh-huh, correct.
15	Q. That's Exhibit 492, correct?	15 Q. Was that an understood term, AAC, for Actual
16	A. Yes.	16 Acquisition Cost at the time?
17	Q. Do you recall that email?	17 A. I used it. I -- I think it was fairly
18	A. Now that I've read it, yes, I do.	18 commonly used.
19	Q. All right. And do you recall having those	19 Q. And it was distinguished from AWP, correct?
20	thoughts and expressing them to your fellow	20 A. Yes.
21	Medicaid pharmacy administrators at the time?	21 Q. Would it be fair to say that AAC is what AWP
22	A. I did send the email.	22 would be if AWP really were an average of wholesale
	Page 179	Page 181
1	Q. Yes.	1 prices to pharmacists?
2	A. And I --	2 A. Assuming that AWP was an average of the
3	Q. But it was a fair reflection of what you	3 actual net costs to the pharmacy, net any sort of
4	thought at the time.	4 discounts that they -- they received, yes. You
5	A. It's a fair reflection of what I thought at	5 know, AWP, in -- when you put it in those terms,
6	the time, it's a fair reflection of what I still	6 yes. It would be actual acquisition cost.
7	think.	7 Q. And if you go down just a little bit farther,
8	Q. The first thing I would like to point you to	8 you indicate to First DataBank, or you indicated to
9	in this email is the -- on the very first page, and	9 First DataBank that there were pharmacies that had
10	the first paragraph of your email to First	10 told you that they would stop supplying some of
11	DataBank.	11 these 428 products if the new AWPs remained in
12	A. Uh-huh.	12 effect, correct?
13	Q. It begins, "since early May."	13 A. Correct.
14	Do you see that?	14 Q. And was that true?
15	A. Let's see.	15 A. As far as I know, it was true. Again, the
16	Q. It's about five minutes down.	16 specifics of which pharmacies or which type of
17	A. Yes.	17 pharmacies, I don't know. I do recall getting
18	Q. And I'll just -- for the record, it reads,	18 calls from both pharmacy providers and also from
19	quote, Since early May, FDB has been reporting to	19 organizations like the Minnesota Pharmacists'
20	state Medicaid agencies, quote, AWPs, close quote,	20 Association that represented pharmacies. And I do
21	for approximately 428 NDCs that are the different	21 recall individuals telling me that, you know, they
22	than the real AWP that is really being reported to	22 were losing money, and they could not continue

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<p>1 supplying the products at that price.</p> <p>2 Q. And then if you go down just a little bit</p> <p>3 farther, you write, quote, While the legislators</p> <p>4 did not define AWP, we believe that their intent</p> <p>5 was it use AWP to mean a single estimate of</p> <p>6 wholesale price as published in a compendia, such</p> <p>7 as Red Book or by First DataBank, closed quote.</p> <p>8 Do you see that?</p> <p>9 A. Yes, I do.</p> <p>10 Q. Did you understand the legislators' intent of</p> <p>11 using the word "AWP" to refer to the published AWP</p> <p>12 in the compendia?</p> <p>13 A. That was my understanding of what the intent</p> <p>14 probably would be.</p> <p>15 Q. If you turn to the next page, you indicate in</p> <p>16 the first full paragraph that the providers who had</p> <p>17 contacted you ranged from independents to chains to</p> <p>18 specialty infusion pharmacies who were complaining.</p> <p>19 Do you see that?</p> <p>20 A. I do.</p> <p>21 Q. Do you recall any of the details of any of</p> <p>22 the complaints you received from any of those</p>	<p>1 for a couple hours, right?</p> <p>2 A. Well, for -- after -- after the lunch break</p> <p>3 here, yes. I went through this, yeah.</p> <p>4 Q. And if you look down at the next paragraph</p> <p>5 after the block quote, you state that, quote, In</p> <p>6 fact, when pharmacy organizations have sought an</p> <p>7 increase in dispensing fees, the AWP spread has</p> <p>8 been pointed out to legislators, closed quote.</p> <p>9 Do you recall that in negotiations with the</p> <p>10 legislature about dispensing fees, the fact that</p> <p>11 there was profit on the ingredient cost was pointed</p> <p>12 out as a reason not to increase dispensing fees?</p> <p>13 A. Yes. This is back in 2000. And I don't</p> <p>14 recall so much the discussions back then, because</p> <p>15 that was before we were trying to lower fees. And</p> <p>16 I don't recall if there were efforts to try to</p> <p>17 increase fees. I know there had been. And there</p> <p>18 may have been, I just simply don't recall.</p> <p>19 And there -- there may have been -- there were</p> <p>20 -- and, again, exactly when all these legislative</p> <p>21 proposals came into place -- it's hard to remember</p> <p>22 now, because the time I was there, every year there</p>
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<p>1 pharmacies?</p> <p>2 A. No. Just as I've just mentioned, I recall</p> <p>3 getting complaints. If I wrote that, I believe it</p> <p>4 to be true.</p> <p>5 And -- but remembering the details of what may</p> <p>6 have been five-minute phone conversations eight</p> <p>7 years ago, sorry, I just don't.</p> <p>8 Q. And in the next paragraph, you indicate that,</p> <p>9 as you put it, almost everyone who is familiar with</p> <p>10 pharmacy reimbursement knows that AWP is "ain't</p> <p>11 what's paid," right?</p> <p>12 A. Yes.</p> <p>13 Q. And back then also, almost everybody who is</p> <p>14 familiar with pharmacy reimbursement knew that AWP</p> <p>15 was "ain't what's paid," right?</p> <p>16 A. Yes.</p> <p>17 Q. Okay. And then at the end of that paragraph,</p> <p>18 you indicate that the spread between AAC and AWP is</p> <p>19 taken into account when determining what to pay for</p> <p>20 a dispensing fee, right?</p> <p>21 A. That's correct.</p> <p>22 Q. And that's what we've just been discussing</p>	<p>1 were a half a dozen to a couple dozen</p> <p>2 pharmacy-related bills. So it's very possible that</p> <p>3 some legislator in 1999 and 2000 was trying to get</p> <p>4 reimbursement increased. There was one effort -- I</p> <p>5 don't remember exactly what it was, where one</p> <p>6 legislator wanted every independent rural pharmacy</p> <p>7 in the state to get an increase.</p> <p>8 But -- so exactly when the discussions</p> <p>9 happened, I don't know. But we had numerous</p> <p>10 discussions with the key -- health care-related</p> <p>11 legislators about this issue.</p> <p>12 Q. And you advised those legislators that</p> <p>13 pharmacies had a profit margin built into the</p> <p>14 ingredient cost of the reimbursement formula that</p> <p>15 made up for the fact that the dispensing fee was</p> <p>16 not sufficient to cover costs plus a profit,</p> <p>17 correct?</p> <p>18 A. That would be correct.</p> <p>19 Q. If you go down to the -- a little bit</p> <p>20 farther, at the very last two sentences of that</p> <p>21 paragraph, it reads, quote, If the AWP spread</p> <p>22 disappears, the dispensing fee may have to be</p>

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<p>1 increased, especially for many of the 428 drugs      2 currently in question. Many of these drugs require      3 some type of compounding or other preparation,      4 close quote.</p> <p>5 Do you recall, whether, in fact, many of the      6 drugs on the NAMFCU list were infusion drugs that      7 required compounding?</p> <p>8 A. I believe many of them were. I don't recall      9 -- the specific details. Obviously, I got the      10 number incorrect. I thought it was 476. But, as I      11 recall, there were a lot of drugs that would have      12 been used in I.V. compounding.</p> <p>13 Q. In fact, I'm going to hand you a copy of      14 Exhibit 587, which is from a related program. It's      15 a Medicare program memorandum. Do you recall that      16 Medicare at the time was also looking to go to use      17 these new DOJ AWP's?</p> <p>18 A. I may have been aware of it. I didn't focus      19 as much on -- on Medicare and -- I mean, this      20 particular document doesn't look familiar      21 immediately. But I -- I may have seen it. But I      22 was obviously more concerned with Medicaid than</p>	<p>1 compounding or other preparation before being      2 dispensed, correct?</p> <p>3 A. Typically. And there are -- sometimes,      4 depending on exactly what it is, you can do some of      5 these drugs. For example, dextrose with sodium      6 chloride. On page 9, the fourth drug down appears      7 to -- or the fourth product down appears to be      8 dextrose sodium chloride, 5 percent dextrose,      9 sodium chloride, 0.9 percent. And, again, if      10 you're watching those medical shows on TV, and you      11 see the doctor tell the nurse, hang a bag of D5W      12 with normal saline, that's what that would be      13 commonly referred to as. And that sometimes is      14 hung by itself, which means it doesn't require any      15 sort of compounding. It's just given by itself.</p> <p>16 But certainly some of the products in here      17 that do contain dextrose or just sodium chloride      18 might be used in compounding other products in      19 various ways. They might be used as a basis for the      20 total parenteral nutrition products -- the compounded      21 products I mentioned. They might be used as the      22 diluent if you were going to reconstitute, say, an</p>
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<p>1 Medicare.</p> <p>2 Q. And if you look at attachment 1 to Exhibit      3 487, it's a list of drugs with an Average Wholesale      4 Price listed for each of them.</p> <p>5 A. Where is that? Started on page 4?</p> <p>6 Q. Yes, sir.</p> <p>7 A. Yes, I see that.</p> <p>8 Q. Does that look familiar -- does that look      9 similar to the list of DOJ or NAMFCU AWP's that you      10 received back in 2000?</p> <p>11 A. I'll just take a look at this. It -- I guess      12 it -- there's some drugs I recognize as being on      13 here, like the acyclovir.</p> <p>14 Q. Uh-huh.</p> <p>15 A. So it -- it might be. But, you know -- I      16 haven't seen that list in many years.</p> <p>17 Q. Do you -- do you recall sodium chloride,      18 dextrose and vancomycin being among the types of      19 drugs that were included on the NAMFCU list?</p> <p>20 A. Not specifically.</p> <p>21 Q. Certainly, those would be drugs that would      22 fall within the category of drugs that required</p>	<p>1 antibiotic, and put it into another solution to run      2 an infusion over half an hour or an hour or      3 something. You might reconstitute the antibiotic,      4 draw it up into a syringe and direct -- and put it      5 into a bag of normal saline, for example, depending      6 on what the product is.</p> <p>7 Q. And that process would be compounding,      8 correct?</p> <p>9 A. That process could be compounding.</p> <p>10 Q. At the bottom of the second page of your      11 email that we have marked as Exhibit 492, you      12 suggest two approaches for resolving the issue      13 being addressed by NAMFCU. That is the difference      14 between AAC and AWP, correct?</p> <p>15 A. Yes.</p> <p>16 Q. Okay. And the first of the suggestions you      17 have is for the state Medicaid agencies to be      18 allowed to work out their own solution by either      19 increasing the discounts off of AWP, adjusting the      20 dispensing fee, establishing MACs or some other      21 method, correct?</p> <p>22 A. Correct.</p>

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UNITED STATES DISTRICT

FOR THE DISTRICT OF MASSACHUSETTS

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IN RE: PHARMACEUTICAL ) MDL NO. 1456  
INDUSTRY AVERAGE WHOLESALE ) CIVIL ACTION  
PRICE LITIGATION ) 01-CV-12257-PBS  
THIS DOCUMENT RELATES TO )  
U.S. ex rel. Ven-a-Care of )  
of the Florida Keys, Inc. )  
v. ) No.06-CV-11337-PBS  
ABBOTT LABORATORIES, INC., )

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(cross captions appear on following pages)

Deposition of HARRY LEO SULLIVAN

Volume I

Nashville, Tennessee

Tuesday, March 12, 2008

9:05 a.m.

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<p>1 things like saline or be it for, you know,      2 sterile irrigation or injection or as a hydration      3 solution or as an add mixture or whatever      4 component to -- whatever service was being      5 delivered in home health, we wanted that to come      6 through the pharmacy program as well and be MACed      7 because those products typically were very cheap.      8 And --      9 BY MR. TORBORG:      10 Q. Were you --      11 A. And in a, in a, you know, home health      12 agency is not doing anything slick or illegal by      13 billing whatever their usual and customary charge      14 is to Medicaid. But those -- if you're care --      15 if you're not careful and people are not      16 cognizant of the costs of those drugs, you might      17 dramatically over-pay.      18 Q. And when you say very cheap, do you      19 mean there are large discounts off of AWP?      20 A. Well, again from my point of view, look      21 at the net acquisition cost, most -- a lot of      22 those things were multi-source items available</p>	<p>1 BY MR. TORBORG:      2 Q. Take this one back.      3 For the record, this is a cover letter      4 dated August 13th, 1996, from June Gibbs Brown to      5 Bruce Fladdock, attaches an OIG report titled      6 Review of pharmacy acquisition costs for drugs      7 reimbursed under the Medicaid prescription drug      8 program at the Florida Agency for Health Care      9 Administration.      10 And then it attaches some comments that      11 Florida provided to the report, which is -- the      12 questions I'm going to be asking you about, Mr.      13 Sullivan, is the last two pages of the document.      14 And I'll ask you some questions in a bit --      15 A. The last two pages of the OIG document?      16 Q. Yeah, the last two pages of the      17 exhibit.      18 A. Okay.      19 Q. Yeah, the very last two pages.      20 A. All right.      21 Q. There is a letter here from Douglas      22 Cook, appears to be the Director of the State of</p>
<p>1 from multiple manufacturers. And I didn't care      2 which manufacturer they used, but I wasn't going      3 to pay more than X.      4 Q. And how would you determine X?      5 A. Again, similar to what we were talking      6 about earlier with, like solid oral dosage forms      7 that become available generically. Find out what      8 the cost is.      9 And, and, and, and in those      10 environments, you know, you might talk to some      11 other different types of providers some people in      12 the home infusion or the home health agency      13 business, and you just say, you know, I'm      14 thinking about putting a MAC on this and this,      15 what do you think? And get, get some kind of      16 feedback.      17 Q. Just show you another document that      18 we've marked previously. I don't want to ask you      19 a whole lot of questions on it. Justice Exhibit      20 84.      21 MR. DRAYCOTT: Pardon me?      22 MR. TORBORG: 84, in the binders.</p>	<p>1 Florida for Health Care Administration.      2 A. Um-hum.      3 Q. Did you ever meet Mr. Cook?      4 A. No, I have not.      5 Q. Did you ever meet Mr. Jerry Wells?      6 A. Oh, absolutely.      7 Q. And have you talked to him a number of      8 times? It sounds like you're pretty familiar      9 with him.      10 A. Yes.      11 Q. And how is that?      12 A. He was, he was one of the deans of the      13 Medicaid pharmacy administrators, very smart,      14 very sharp, in a very dynamic, difficult-to-      15 manage state from a Medicaid standpoint. Very      16 outspoken, very knowledgeable. Somebody that      17 you, you'd bounce things off of. Maybe not      18 always agree, but bounce things off of.      19 Q. In the second page of Mr. Cook's      20 letter, first paragraph, I'll read it into the      21 record, if you would follow along, Mr. Cook      22 wrote, In general products and associated</p>
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<p style="text-align: right;">Page 122</p> <p>1 intravenous fluids also continue to be      2 problematic. Manufacturers offer contracts to      3 most vendors providing very favorable pricing and      4 terms, but manufacturers continue to market small      5 quantities of those, of these through      6 conventional sources and report single-unit      7 pricing through the national data sources. Any      8 assistance your office might offer in      9 standardizing pricing in this market would be      10 beneficial.</p> <p>11       Do you see that?</p> <p>12       A. Yes.</p> <p>13       Q. Do you have an understanding of what      14 Mr. Cook is saying?</p> <p>15       A. He's wanting the federal government to,      16 to MAC these things instead of take the heat for      17 MACing them himself.</p> <p>18       Q. Okay.</p> <p>19       A. I don't mean to -- that's what it      20 appears to me. I don't mean to call him chicken,      21 but -- and it's not necessarily a bad approach to      22 take. It's easier, if you're -- for example, if</p>	<p style="text-align: right;">Page 124</p> <p>1           MR. DRAYCOTT: Objection.      2 BY MR. TORBORG:      3       Q. What's your understanding of what he      4 means by that?      5       A. Well, it could be -- well, again I      6 think he's leaving it up to the, to the Feds to      7 determine whether -- and there is -- this has      8 always been a, a point of confusion in claims      9 processing systems, does a, you know, a 500 ML      10 bottle of normal saline solution count as \$10      11 divided by one or \$10 divided by 500? A      12 reconstitutable antibiotic like Rocephin counts      13 as one. What does the dilutant that you put in      14 there, the 200 cc's or whatever it is that you      15 put in there to dilute that powdered antibiotic,      16 is it one or, or 20? And do -- so does the      17 provider bill me 20 units or one unit? If I set      18 up in my system divided by 500, then they bill me      19 one unit, because they're billing by the bottle,      20 they're shorted, I'm to the good. In the office      21 it could happen. I could get, if I set the units      22 up wrong and they bill 500 and I've got it priced</p>
<p style="text-align: right;">Page 123</p> <p>1 your home health agencies in your state, you      2 know, are very politically connected, have a      3 strong lobby, and will go to war over you      4 implementing this policy, then having the federal      5 government do it for you and you being able to      6 say, I'm going to lose state match if I don't      7 comply, really shifts a lot of the fire to      8 another source.</p> <p>9           MR. DRAYCOTT: Dave, I didn't want to      10 interrupt the witness, but I need to interpose an      11 objection at the end of your question.</p> <p>12        MR. TORBORG: Okay.</p> <p>13        A. And I'm just -- you know, I'm just      14 guessing, the way this is written. I don't know      15 what he was -- his motivation was.</p> <p>16 BY MR. TORBORG:</p> <p>17        Q. And he talks about reporting single-      18 unit pricing.</p> <p>19        Do you understand what he means by      20 that?</p> <p>21        A. Yes.</p> <p>22        Q. What's he mean by that?</p>	<p style="text-align: right;">Page 125</p> <p>1 as one, then they'll be paying 500 times that.      2           So I think this, this gets at not only      3 the question of pricing and a MAC, is what he's      4 asking for, but also gets it and you tell me what      5 the units should be.</p> <p>6        Q. Do you know what he is talking about      7 when he talks about manufacturers reporting      8 single-unit pricing?</p> <p>9        MR. DRAYCOTT: Objection.</p> <p>10        You can answer.</p> <p>11        A. Well, I, I just -- no, I don't know      12 what he's saying. I could guess but I don't know      13 what he means by that.</p> <p>14        Again I think he's asking for clarity      15 on units and MAC and he's wanting somebody else      16 to do it for him.</p> <p>17 BY MR. TORBORG:</p> <p>18        Q. Were you aware when you were the      19 director of pharmacy services of Tennessee that      20 manufacturers were offering very favorable      21 pricing for injectable products in IV fluids?</p> <p>22        MR. DRAYCOTT: Objection.</p>

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1 A. Ah, yes. 2 MR. TORBORG: I would like to mark this 3 as the next exhibit. 4 (Exhibit Abbott 575 marked.) 5 MR. DRAYCOTT: What's the number, 6 please? 7 THE REPORTER: 575.	1 A. Yes. Yes. 2 Q. The next page, rationale for the 3 change, it states, Discounts from the referenced 4 pharmaceutical pricing schedule, known as average 5 wholesale price, vary by product class. 6 Were you aware of that?
8 BY MR. TORBORG: 9 Q. For the record, what I have marked as 10 Abbott Exhibit 575 bears Bates Nos. ACMDL 77735 11 through 36. 12 Mr. Sullivan, I'm sure you're probably 13 not aware of this document, but I wanted to ask 14 you some questions about it, nonetheless. 15 Let me verify that you are not familiar 16 with this document, relates to Kansas?	7 A. Yes. 8 Q. Okay. And when they use the word 9 product class, do you know what they're talking 10 about there? 11 A. Drug class, I assume. 12 Q. What is that? 13 A. Well, not necessarily drug -- 14 Q. What different drug classes are there? 15 A. No, I, I -- well, it's a very broad 16 statement. It, it could be -- it then talks 17 about IV vehicles and irrigation solutions, so I 18 would assume that the first sentence is talking 19 about those type of products rather than specific 20 drugs.
17 A. That's correct. 18 Q. Okay. There is a contact person that's 19 listed there on this document, Gene Stevens. Do 20 you know who that is? Have you had contact with 21 him? 22 A. Yes.	21 Q. Then it goes on to say, Generally 22 intravenous vehicles and irrigation solutions are
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1 Q. Okay. Is he a pharmacy administrator 2 for the State of Kansas? 3 A. Yes. 4 Q. And have you met Joyce Sugrue? Does 5 that name sounds familiar? 6 A. No. 7 Q. S-U-G-R-U-E? 8 A. No, I don't recognize that name. 9 Q. Okay. Under -- there, the very last 10 part of the page, there is a final policy where 11 it states, Effective of dates of service 1/1/95, 12 all sterile irrigation solutions and all large 13 volume parenteral and small volume parenteral 14 fluid replacement in vehicles for intravenous 15 drug administration which are billed as pharmacy 16 claims will be reimbursed at AWP less 50 percent. 17 A. Right. 18 Q. Paren, inhalation solutions are not 19 included in this reimbursement change, end paren. 20 And then there is -- the next page -- let me ask 21 you if you understand what they're saying there. 22 Does that make sense to you?	1 available at much greater discounts than are 2 other pharmaceuticals. This is one of the three 3 methods used to reduce expenditures in the 4 pharmacy program. 5 Were you aware that generally 6 intravenous solutions and irrigation solutions 7 were available at much greater discounts than 8 other drugs? 9 A. Um, generally, yes. Because -- but it 10 would depend on are you a, a hospital? A 11 doctor's office? An outpatient surgery clinic? A 12 home health company? Or a retail pharmacy. 13 Q. Those different customers pay different 14 amounts? 15 A. Or a nursing home, even. 16 Yes. 17 Q. And could the amounts paid be, in your 18 experience, radically different? 19 MR. DRAYCOTT: Objection. 20 A. Yes. 21 BY MR. TORBORG: 22 Q. And when you had situations like that,

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<p>1 when -- let me step back.      2 All of those type of companies could      3 file claims to the Tennessee Medicaid program;      4 right?      5 A. Yeah, there's an enrollment process for      6 providers, but pretty much open to anybody who,      7 who wanted to enroll.      8 Q. And all of those companies could      9 potentially file claims for reimbursement for      10 drugs; is that right?      11 A. You talking about providers now?      12 Q. Providers.      13 A. Yes.      14 Q. And some of those providers paid more      15 than other providers for drugs; right?      16 A. Yes.      17 Q. And sometimes, as we talked about, --      18 A. However, let me -- I did mention      19 hospital, so, yeah.      20 Q. Okay. Let's take hospitals out of the      21 equation.      22 A. Yeah, let's take them out. There's a</p>	<p>1 you know, dealing with a Medicaid program, this      2 is not a, not a new concept, but I'm sure in a      3 lot of instances those sorts of products are      4 eaten by the provider, if -- or the difference      5 between the MAC and their cost is eaten. And      6 they have to make a determination if it's worth      7 it to, to provide that service.      8 Q. Sometimes the pharmacy --      9 A. And typically, typically.      10 Q. And sometimes they don't.      11 A. You could have a laundry list of things      12 you're billing for.      13 Q. Um-hum.      14 A. You're just not billing for one sterile      15 solution or little IV solu -- there is drugs it      16 in, there's services in it, there is supplies,      17 there's bandages, and, you know, all that.      18 And, you know, you may just figure a      19 little hit on the difference between the MAC and      20 whatever you're -- you pay. But again, by and      21 large the MAC's set, so it's not a disincentive.      22 Q. You would look at the big picture.</p>
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<p>1 per diem.      2 Q. But the others ones you mentioned.      3 A. Yeah.      4 Q. They would all file payments -- file      5 claims for payment; correct? For pharmacy      6 claims.      7 A. Yes. But there may be -- yes. But      8 there may be situations where, you know, the home      9 health agency may subcontract with a pharmacy who      10 is, so -- yeah, but eventually, yes.      11 Q. And they could pay different prices for      12 drugs.      13 A. Yes.      14 Q. How would you deal with that from a      15 policy perspective in trying to decide how much      16 to pay?      17 A. Well, you know, we took a pretty hard      18 line, and, and again tried to be fair when you      19 set a MAC, and take into account all the      20 different provider -- the ripple effects of      21 setting that MAC.      22 Um, but I'm sure -- and I'm sure that,</p>	<p>1 A. Try to.      2 Q. And you referred earlier to the      3 National Pharmaceutical Council reports?      4 A. Yes.      5 Q. And those, among other things, would      6 set forth the state's payment methodology for      7 drugs.      8 A. They would -- yeah, they would report      9 what those --      10 Q. What the state's told them --      11 A. Yes.      12 Q. -- it was?      13 A. Yes.      14 Q. And do you know if a methodology      15 specific to IV drugs such as we see in Kansas      16 would be put in there?      17 A. I don't know. I don't know if that was      18 part of the survey or not. I --      19 Q. But if it was in there, everyone who      20 reviewed the NPC reports could see what Kansas --      21 A. Sure.      22 Q. -- had done?</p>

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1	A. Sure.	1	A. I honestly do not remember.
2	MR. TORBORG: Why don't we take a	2	Q. Have you ever heard of the company Ven-
3	break.	3	A-Care?
4	VIDEOGRAPHER: Going off record. End	4	A. No, I really -- the logo looks
5	of tape 2. Time now is 11:31.	5	familiar, but I don't know by what context I
6	(Recess.)	6	would know them.
7	(Exhibit Abbott 576 marked.)	7	Q. Do you recall that some company was
8	VIDEOGRAPHER: Back on record.	8	working on a project, a continuing education
9	Beginning of Tape 3. Time now is 11:49.	9	project --
10	BY MR. TORBORG:	10	A. No.
11	Q. Welcome back, Mr. Sullivan.	11	Q. -- concerning these kind of drugs?
12	A. Yeah.	12	A. No.
13	Q. I have marked and handed you as Abbott	13	You, you have to know that during the
14	Exhibit 576 a document that bears the Bates Nos.	14	course of a week you'll get, in a position like
15	VAC-MDL 75533 through 66.	15	that, you'll get all kinds of requests for
16	For the record, and so that you know,	16	surveys and stuff like this.
17	this is a document that was produced by the	17	Q. If we go to the page preceding this
18	relator in this case, a company called Ven-A-Care	18	page, page ending 538, there is a document titled
19	of the Florida Keys, Inc., and particularly these	19	Response to National State Medicaid Reimbursement
20	were documents that were looks like contained in	20	Survey. Contact person is -- that's you; right?
21	a folder titled Tennessee. And as you were the	21	A. Yes.
22	director of pharmacy services at Tennessee, I	22	Q. And then it appears as though you gave
	Page 135		Page 137
1	thought I might ask you about some documents	1	him some information relating to Tennessee's
2	contained therein.	2	reimbursement for IV drug reimbursement and TPN
3	A. Okay.	3	reimbursement. Do you see that?
4	Q. In particular I would like to start	4	A. Yes.
5	with the Bates page ending 539. This is an	5	Q. And in particular IV reimbursement was
6	October 24th, 1994 letter from Zachary Bentley to	6	AWP minus 8 percent plus a \$3.91 dispensing fee
7	Leo Sullivan regarding state policy and	7	per ingredient.
8	methodology for reimbursement of intravenous	8	And was that the standard, from your
9	solutions and injectable drugs. Do you see that?	9	recollection, was that the standard reimbursement
10	A. Yes, sir.	10	rate that Tennessee used for drugs at that time?
11	Q. If you would take a look at that	11	A. No.
12	document. Let me know if you recall it and then	12	Oh, this, this information is not
13	I'll have some questions for you about it.	13	accurate at all.
14	A. Okay.	14	Based on the date 11/29/94 we're almost
15	Okay.	15	a year into TennCare. I wasn't paying for any,
16	Q. Mr. Sullivan, do you recall this, this	16	any of these products. The MCOs, through their
17	particular page?	17	PBMs, or however they set up reimbursement, for
18	A. I really don't.	18	paying for this. So somebody, sounded like
19	Q. Do you recall ever having any	19	somebody just got an old NPC book and wrote this
20	correspondence or communications with Zachary	20	down. I don't remember talking to them. I may
21	Bentley or anyone else that you understood to be	21	have. But this is not accurate information.
22	affiliated with Ven-A-Care of the Florida Keys?	22	The state didn't have a policy for IV

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<p>1 drug reimbursement during this time period. We 2 paid capitated fees to MCOs.</p> <p>3 Q. Do you believe it's possible that you 4 never even had a discussion with anyone else from 5 Ven-A-Care?</p> <p>6 A. I -- you know, you have so many calls 7 and so many -- I mean all day long, every day, I, 8 I'm not going to say that I absolutely did not 9 talk to these people. It looks like, too, on 10 number 3 it says price negotiated with various 11 provider of TennCare system. Somebody's writing 12 something down here that didn't, didn't even 13 understand TennCare. I mean these prices -- 14 whatever, whatever reimbursement there was in 15 this time period, 11/29/94, was strictly between 16 the MCO and their provider network and it would 17 vary from MCO to MCO.</p> <p>18 I mean at this point in time there were 19 12 different MCOs in TennCare. Nobody could fill 20 out this form for TennCare. There would be 12 21 forms, and it wouldn't be me as the contact 22 personal, it would be the medical director of the</p>	<p>1 HFCA approved the waiver. 2 The -- we could negotiate, we could 3 have it all set and ready to go when HFCA did 4 give that approval, consequently, then, the MCOs 5 were unable to fully execute provider contracts 6 with physicians, hospitals or anybody else, until 7 they had a contract with TennCare.</p> <p>8 So it was a cascade of events that 9 started on 11/22/93, implement and go live a 10 month and a half later with 1.4 million lives. 11 Just ridiculous implementation schedule.</p> <p>12 But it, but it happened that way. So 13 what happened on day one with the pharmacy 14 program was just, just fill claims. Just pay 15 claims. I mean pharmacists, the whole first 16 couple of months of TennCare, were filling 17 prescriptions on faith, not even know who to 18 submit the claim to or if and when or what the 19 amount of reimbursement would be.</p> <p>20 By mid '94 and on into early '95, we 21 eventually evolved into a situation where there 22 were still at that time maybe 12 MCOs, with six</p>
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<p>1 MCO or the pharmacy director of that MCO or the 2 PBM.</p> <p>3 Q. Did the MCOs in TennCare, did they have 4 different methodologies for reimburse -- for 5 paying for drugs, or did they all use the same 6 one?</p> <p>7 A. Right out of the gate in January, I 8 think they all pretty much piggybacked what we 9 had in place at December 31, 1993, but by midyear 10 -- and the, and the reason that is is because the 11 waiver wasn't even approved until November 22nd.</p> <p>12 Q. Of '94?</p> <p>13 A. Of '93.</p> <p>14 Q. '93?</p> <p>15 A. And we went live January 1st, '94, you 16 know, a month and a half later.</p> <p>17 What we had done prior to whatever 18 approval, the whole 1993, was identify potential 19 MCOs, give them contracts that outlined their 20 responsibilities and even actuarial information 21 on capitation rates, but we couldn't fully 22 execute the contracts with those 12 MCOs until</p>	<p>1 different PBMs handling those, and then later on 2 it evolved to, you know, some of these MCOs went 3 bust or quit or whatever, and you had eight, 4 maybe eight MCOs dealing with two or three PBMs 5 and 95 percent of the enrollment was actually 6 under one PBM by the way the enrollment fell with 7 those eight MCOs, so it -- this is somebody, 8 somebody fudged this to just get a report done is 9 what it looks like to me.</p> <p>10 Q. Under the state policy for DPM 11 reimbursement AWP plus 33 percent, do you recall 12 if that was a policy that Tennessee had before 13 TennCare was implemented?</p> <p>14 A. I don't know where they would have 15 gotten that. TPM reimbursement was MACed. At 16 some point in time it became MACed, TPM Solutions 17 did. But it certainly was not AWP plus 33 18 percent. You know, cost plus 33 is closer to it.</p> <p>19 Q. Do you recall ever discussing at the 20 meetings you had with other state Medicaid 21 representatives, pharmacy representatives, the 22 subject of any lawsuit relating to average</p>

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<p>1 Q. Mr. Sullivan, I have handed you what we      2 have marked as Abbott Exhibit 577. It has the      3 Bates Nos. HHC 002-0423 through 30.      4 If you would take a look at that just      5 to see if that's a publication that you're aware      6 of.</p> <p>7 A. Yes, it is. I got these.</p> <p>8 Q. Okay. Can you tell, can you tell us      9 what this, what this document is.</p> <p>10 A. Um, just -- I think -- well, let's see.      11 Appears, I don't know, every couple of months, I      12 guess. Just news. There were some of my peers      13 on an advisory board who would send in various      14 information, updates or particular issues that      15 are going on in different states, Medicaid      16 pharmacy programs. It was Medicaid specific.</p> <p>17 Q. And do you know who all received these      18 pharmacy or Medicaid pharmacy --</p> <p>19 A. I think all the --</p> <p>20 MR. DRAYCOTT: Objection.</p> <p>21 A. -- pharmacies directors.</p> <p>22 BY MR. TORBORG:</p>	<p>1 bulletin notes, reimbursing -- well, let me, let      2 me back up.</p> <p>3 Do you know who wrote these articles,      4 generally speaking?</p> <p>5 A. No, I didn't -- there is editor on      6 here. I don't know her and I -- I know -- I      7 certainly knew or got to know, after this time      8 period, most of these people on the advisory      9 panel. They're all Medicaid pharmacists.</p> <p>10 Q. On page 454.</p> <p>11 A. On page 2, yeah.</p> <p>12 Q. Do you have any idea where the editor,      13 listed here as Karen Nardi, how she obtained her      14 information for articles of this magazine?</p> <p>15 A. I, I assume -- no, I don't know. I      16 would assume she interviewed folks.</p> <p>17 Q. Did you -- were you ever interviewed      18 for this publication?</p> <p>19 A. I might have been.</p> <p>20 I -- certainly not at this time period.      21 I had just started work for the state      22 at this time, but I might have been, in</p>
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<p>1 Q. And what, what makes you think that?</p> <p>2 A. Because that's -- I believe that was      3 pretty much the -- one of the audiences targeted      4 with it.</p> <p>5 Q. And this particular bulletin is dated      6 January-February of 1990.</p> <p>7 A. Um-hum.</p> <p>8 Q. Correct?</p> <p>9 A. Yes.</p> <p>10 Q. And that's when you would have been the      11 director of pharmacy services you would have been      12 director of pharmacy services of Tennessee at      13 that time.</p> <p>14 A. Yes.</p> <p>15 Q. And this has an article titled      16 Revisiting Medicaid reimbursement for home IV      17 drug therapy. Do you see that?</p> <p>18 A. Yes.</p> <p>19 Q. And in particular I have a few      20 questions for you on this.</p> <p>21 A. Okay.</p> <p>22 Q. The first column, first page, the</p>	<p>1 subsequent issues.</p> <p>2 Q. Here, first column, first page, it      3 says, Reimbursing adequately and efficiently for      4 home IV drug therapy has been a continuing      5 problem for many Medicaid pharmacy      6 administrators. Do you see that?</p> <p>7 A. Um-hum, yes.</p> <p>8 Q. Was this a problem that you were, that      9 you were confronting, or not?</p> <p>10 A. Yeah, I think, because there's so many      11 inlets to the system from the provider side that      12 you have to be very vigilant of, you know, how      13 many claims get in the system. And whether or      14 not they're paid or rerouted or denied or how      15 they're handled.</p> <p>16 Q. Then later on in that paragraph it      17 states, a number of states are concerned that      18 their current reimbursement methodology for home      19 IV therapy is inadequate and are trying to      20 develop improved systems which will permit them      21 to pay providers more quickly while avoiding      22 overpayment. Was that -- did you ever have</p>

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1 wholesale price. 2 A. The only thing I remember vaguely is, 3 and it didn't really -- it didn't really impact 4 me, and I don't recall if Tennessee was a part of 5 it, but it was some suit that did involve I 6 believe Abbott and maybe some other folks, maybe 7 TAPP, but I'm not sure about that, where there 8 was an allegation, and I don't know, ultimately 9 the -- you know, it may have been settled in some 10 settlement, and I don't know about blame or guilt 11 or any of that, but my memory is that it involved 12 selling injectable type drugs or products to 13 physicians to be administered in the physician's 14 office. 15 And I guess the allegation was that the 16 AWP was either inflated or well above the actual 17 cost to the physician for the product.	1 involved in that case. I just remember hearing 2 about it. 3 Q. When did you first start hearing about 4 it? 5 A. Oh, gosh, I don't know. Sometime in 6 the Nine -- mid Nineties, I would guess. I'm not 7 sure. 8 Q. Was it something that you recall being 9 discussed at the national symposium -- 10 A. No. 11 Q. -- meetings? 12 A. No. Again this is, this had to do with 13 physician offices or -- 14 Q. Where did you learn about it? 15 A. Through -- I, I would -- you know, 16 trade journals, you know, news. I had no direct 17 involvement in it. The industry. I remember 18 just rumblings through the industry that -- it 19 seems to me there was a significant settlement. 20 I don't, I don't know what it was. 21 Q. Did you -- what types of news, 22 periodicals, did you review in your work as the
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1 you'll make a killing using my drug, and it was - 2 - 3 Q. Have you heard the term marketing to 4 spread? 5 A. Yes. 6 Q. Is that what you're talking about? 7 A. Yes. 8 Q. Okay. I'm sorry. I think I may have 9 cut you off. 10 A. But I don't know if the, but I don't 11 know if the allegations were just that the price 12 had been lowered so much or if the AWP had been 13 finagled or -- with the publishers of AWP or 14 both, I don't know what the outcome was or the 15 real allegations. I was just aware of some -- 16 and it, and it had to do with physician's offices 17 is my recollection. 18 Q. Did it relate to Lupron? Does that 19 ring a bell? 20 A. That certainly was one. And also 21 injectable other solutions, I think, as well. 22 But I don't, I don't -- like I said, I never got	1 director of pharmacy services? 2 A. Um, you know, everything from clinical 3 journals to trade, trade journals. 4 Q. Do you recall any particular ones? 5 A. Oh, gosh. 6 You know, managed care pharmacy things. 7 Pharmacy, I'm sorry, drug topics, you know, stuff 8 from the APHA. Regular news, CBS, NBC, CB -- or 9 ABC. 10 Q. Did you -- did your office have a 11 subscription to any of these? 12 A. Yes. Probably -- well, all the 13 pharmacy journals, I think most of those -- well, 14 I'll say all the ones that are free. Most of 15 them were free. But all the ones that are free, 16 we -- I don't think I ever paid anything, could 17 get the state to pay for anything, but -- 18 Q. Okay. 19 MR. TORBORG: Going to mark this as 20 another exhibit. 21 (Exhibit Abbott 577 marked.) 22 BY MR. TORBORG:

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<p>1 concerns on whether or not the payment for these 2 kind of therapies was, was adequate?</p> <p>3 A. Well, my opinion, particularly in the, 4 in the home health arena, was -- and during this 5 specific time period, the growth in Tennessee was 6 such of those type of providers that it wouldn't 7 -- that wouldn't -- not lead you to believe that 8 the reimbursement for Medicaid was inadequate.</p> <p>9 When people are hollering and screaming 10 or you have trouble getting providers to take 11 care of your patients is when that was more 12 likely a concern.</p> <p>13 Q. Well, do you know when the home 14 infusion business really started taking off?</p> <p>15 A. Well, it certainly took off in the 16 early Nineties. And I can't remember -- and 17 Tennessee was a little bit different because we 18 very purposely avoided expansion of home 19 community based services under the Medicaid 20 program because the vast majority of the patients 21 who would receive those services were dual 22 eligibles, which meant they had Medicaid and</p>	<p>1 they're talking about when they talk about a 2 compounding fee?</p> <p>3 A. Yes.</p> <p>4 Q. And what, what is that?</p> <p>5 A. Well, certain, be it -- I mean you can 6 compound IV drugs if you have the right equipment 7 and filters and hoods to keep it, make it a 8 sterile product.</p> <p>9 And you can compound drugs for 10 inhalation. If you have, again, the right 11 equipment, similar to what would be in a 12 hospital, to, to handle sterile products.</p> <p>13 And you take the raw ingredient and 14 mimic whatever, generally, the brand name or the 15 innovator product was.</p> <p>16 Q. And do you know in Tennessee, either 17 before TennCare or after TennCare was paying a 18 compounding fee for IV? Do you know if that was 19 something that was being paid?</p> <p>20 A. Ah, no. But there's, there's ways to 21 pay it without, without having a separate -- you 22 know, I noticed on here that one form is for</p>
<p>1 Medicare. And Medicare home health was, was 2 truly exploding. We had hundreds of providers in 3 Tennessee of home health services. I dare say 4 there's, you know, maybe 20 now. Because there 5 was, there was indeed a bonanza on the Medicare 6 side in Tennessee. Other states didn't face it 7 quite as -- if they had chosen to expand or had 8 very aggressive home community-based services 9 through Medicaid, might have had a little bit 10 different policy issues. We purely shifted to 11 Medicare, cost shifted to Medicare, with the 12 duals. And so it wasn't maybe not as, as intense 13 on a Medicaid issue in Tennessee as it might be 14 elsewhere is what I'm saying.</p> <p>15 Q. The page starting with -- at 425 and 16 then going over to 426, there is a discussion of 17 what some states are doing in the home IV 18 reimbursement area, Minnesota indicates 19 compounding or a dispensing fee of \$8 for IV 20 drugs, and then Washington indicates that they're 21 paying a compounding amount, Ohio as well. 22 Do you have an understanding of what</p>	<p>1 payment, one form is for reimbursement of 2 supplies, one form is for -- you know, they're, 3 they're making a variety to submit multiple 4 forms. And I wouldn't -- I can't tell you a 5 specific product or specific time period, but one 6 of my strategies was in issues like this, where 7 compounding was involved, I didn't want to go 8 down the road, at least in the early Nineties, of 9 getting into paying for compounded prescriptions, 10 because that can -- that could range from a 11 sterile product all the way down to an ointment, 12 okay?</p> <p>13 And, and our claims reimbursement 14 system hadn't evolved to the current NCPDP 15 sophistication of today. So it was very hard to 16 put in a, a set compounding fee for what, what 17 products?</p> <p>18 One may take a minute to make, one may 19 take an hour and a half.</p> <p>20 So getting back to, to the MAC issue, 21 some, sometimes for certain products in this 22 arena, you would take that into account for the</p>
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<p>1 MAC.</p> <p>2 For example, I might say, I'm not 3 paying for the tape that you use to hold the IV 4 needle into place. I'm not paying for the IV 5 needle or the tube set. I'm not going to -- I 6 don't want bills for that. I know you've got to 7 do it to administer this drug. So we're going to 8 add on the cost of this drug X, because I know 9 this, this and this always goes with it, and I 10 know there is a fixed cost for that, but I don't 11 want five bills. I want 10 different places. 12 Bill me for the drug. And I'll make sure that 13 the -- whatever the MAC is incorporates all your 14 other costs. And you have to talk with providers 15 and know what that is. I mean, you know.</p> <p>16 Q. So, in short, you would use the payment 17 for the drug itself to cross-subsidize other 18 things that might need to be paid to fairly --</p> <p>19 A. And that would include compounding.</p> <p>20 Q. And it may include nursing services 21 that were not included, things of that nature?</p> <p>22 A. (Nodding yes.)</p>	<p>1 addressed in this letter. I don't know. It 2 seems to talk about different states, but I'm 3 sure there were varying levels of complexity in 4 the billing process, and what was and wasn't 5 billable and what was and wasn't included, but I 6 don't know it and I didn't discuss it with folks.</p> <p>7 Q. Have you heard the term cross-subsidy 8 or cross-subsidization in the context of pharmacy 9 reimbursement?</p> <p>10 A. No, not -- no, I haven't.</p> <p>11 Q. I'm going to show you another, another 12 -- going to mark that as another exhibit.</p> <p>13 MR. TORBORG: I think this is 578. (Exhibit Abbott 578 marked.)</p> <p>14 BY MR. TORBORG:</p> <p>15 Q. For the record, what we have marked as 16 Exhibit 578 bears the Bates numbers HHC 002-0400 17 through 407. It's another Medicaid pharmacy 18 bulletin. This one dated January-February of 19 1988.</p> <p>20 Mr. Sullivan, if I could ask you to go 21 to Bates page ending in 402. In particular the</p>
<p>1 Q. Did anyone in the federal government 2 ever tell you that you were not allowed to do 3 that?</p> <p>4 A. No.</p> <p>5 Q. And if they had told you that, what 6 would you have said?</p> <p>7 A. That I wasn't allowed to pay for 8 compounding or --</p> <p>9 Q. That you weren't allowed to use the 10 payment for the drug to cross-subsidize those 11 other services or supplies.</p> <p>12 A. If they had told me I couldn't do it, 13 what would I do?</p> <p>14 Q. Yes.</p> <p>15 A. I would have had to have found another 16 way to, to handle the billing.</p> <p>17 Q. But they never told you that.</p> <p>18 A. No.</p> <p>19 Q. Do you know if other states were doing 20 -- were adopting similar type strategies to run 21 the programs?</p> <p>22 A. No, I don't -- I mean it may be</p>	<p>1 discussion on the first full paragraph about 2 Montana Medicaid. Do you see that?</p> <p>3 A. Yes.</p> <p>4 Q. Where it says, Similarly, Montana 5 Medicaid compensates for the additional time and 6 expense of dispensing compounded drugs by 7 allowing the provider's usual and customary 8 charge up to 2.5 times the cost of ingredients, 9 paren, reimbursement for other outpatient drugs 10 is a lower of AWP minus 10 percent, or the cost 11 of the drug, end paren. Do you see that?</p> <p>12 A. Yes.</p> <p>13 Q. Is that the, the type of thing that 14 Tennessee was doing?</p> <p>15 A. It's a different approach to -- yeah. 16 Make -- paying the provider for the, for the 17 compounding without -- and setting a limit on 18 what I will pay up to two and a half percent. 19 It's just a different, different twist.</p> <p>20 Q. Does it -- does this refresh your 21 recollection about any other types of approaches 22 like this that other states were using?</p>

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<p>1 -- there is a cost to dispense. It's kind of      2 like AWP, it's inflated. Because there's so many      3 factors come into the light switch, the --      4 whether or not your little drugstore and you      5 offer health insurance to your six employees.      6 Heck, if you offer health insurance to six      7 employees, it's going to be very expensive. And      8 that's figured into the cost to dispense. So      9 it's very variable.</p> <p>10 Q. Let me ask you about one more document      11 before we break for lunch, if that's all right.</p> <p>12 A. Sure.</p> <p>13 Q. Do one more?</p> <p>14 A. I'm good.</p> <p>15 Q. Let me ask you about Exhibit 21 in this      16 binder.</p> <p>17 For the record, this is a document      18 dated in 2002, August 2002, titled Determination      19 of the Cost of Dispensing Pharmaceutical      20 Prescriptions for the Texas Vendor Drug Program.      21 It's prepared for the Texas Health and Human      22 Services Commission.</p>	<p>1 pretty much hands on, and the normal rate paid a      2 pharmacist drives up that cost when -- as opposed      3 to a technician filling a prescription for some      4 tablets.</p> <p>5 Q. If I could ask you to go to page 43 of      6 this study. The third full paragraph starts      7 with, Although the analysis. Do you see that?</p> <p>8 A. Yes.</p> <p>9 Q. The last sentence of that paragraph      10 states, It is therefore possible that some      11 pharmacies could very well have dispensing costs      12 in excess of \$40 per prescription. And then the      13 next paragraph states, Under current policies the      14 Health and Human Services Commission reimburses      15 for intravenous prescriptions and a dispensing      16 fee plus ingredient reimbursement formula for      17 traditional retail prescriptions.</p> <p>18 Although dispensing costs at      19 intravenous pharmacies appears to be in excess of      20 the current base dispensing fee of \$5.27, this      21 reimbursement methodology has been accepted by      22 these pharmacies likely due to the inventory</p>
Page 191	Page 193
<p>1 In particular I'd like to ask you to go      2 to the third page of this exhibit under Summary      3 of Findings.</p> <p>4 The last bullet there states, Average      5 dispensing costs at certain pharmacy specialties      6 was observed to be higher than dispensing at,      7 quote, typical, end quote, retail pharmacies. In      8 particular, we noted higher dispensing costs      9 associated with pharmacies that provide services      10 related to the dispensing of intravenous, home      11 infusion and compound prescriptions.</p> <p>12 Do you see that?</p> <p>13 A. Yes.</p> <p>14 Q. Did you become aware, Mr. Sullivan,      15 that intravenous, home infusion and compounded --      16 I'm sorry. Strike that.</p> <p>17 Did you become aware that pharmacies      18 providing services relating to intravenous, home      19 infusion and compounded prescriptions had a      20 higher cost to dispense?</p> <p>21 A. Yes. I wouldn't say become aware. I      22 mean it's -- a pharmacist has to do compounding,</p>	<p>1 management add-on to expense dispensing fee,      2 paren, which can be significant on the expensive      3 drugs traditionally dispensed in intravenous      4 forms, end paren, and the margin on ingredient      5 reimbursement, which has allowed pharmacies to      6 offset a shortfall from a base dispensing fee.</p> <p>7 Do you see that?</p> <p>8 A. Yes.</p> <p>9 Q. Do you have an understanding of what      10 they're talking about there?</p> <p>11 A. Yes.</p> <p>12 Q. And did you have any experience talking      13 with providers of intravenous therapy, home      14 infusion therapy, that they were accepting an      15 insufficient dispensing fee because of the margin      16 allowed on the ingredient reimbursement?</p> <p>17 A. I wouldn't say specifically in those      18 terms, but I, but I certainly had discussions      19 with these types of providers on how much I've      20 got in it and how much you're paying me.</p> <p>21 And not specific numbers, but that --      22 and disparities, too, I think were one of the</p>

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UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF MASSACHUSETTS  
IN RE: PHARMACEUTICAL  
INDUSTRY AVERAGE  
WHOLESALE PRICE LITIGATION  
MDL NO. 1456  
NO. 01-CV-12257-PBS  
JUDGE PATTI SARIS  
MAG. MARIANNE BOWLER

THIS DOCUMENT RELATES  
TO U.S. EX REL.  
VEN-A-CARE OF THE FLORIDA  
KEYS, INC. V. ABBOTT  
LABORATORIES, INC., ET AL.,  
NO. 06-CV-11337-PBS

VIDEOTAPED DEPOSITION OF MARY  
JULIA TERREBONNE, 6080 ESPLANADE AVENUE,  
BATON ROUGE, LOUISIANA 70806, TAKEN IN THE  
OFFICES OF LOUISIANA DEPARTMENT OF HEALTH &  
HOSPITALS, BIENVILLE BUILDING, 628 N. FOURTH  
STREET, BATON ROUGE, LOUISIANA 70806, ON THE  
31ST DAY OF MARCH, 2008.

<p style="text-align: right;">Page 30</p> <p>1 claims data, that kind of thing?      2 A. Right.      3 Q. How about if you had an e-mail from a      4 provider or a provider had a question concerning      5 payment rates in, say, the mid-1990s. Is that the      6 kind of thing that you would keep?      7 A. I would probably keep it if it were      8 related to some type of state plan that we may be      9 submitting, but just to keep it, if it doesn't      10 pertain to anything, I wouldn't keep it.      11 Q. Do you know if the department has a      12 formal document retention policy?      13 A. I do not.      14 Q. Do you have a general understanding of      15 what it is that the United States government, as      16 the plaintiff in this action, alleges that Abbott      17 did wrong?      18 A. I do not.      19 Q. Is it your understanding that the case      20 relates to the subject of average wholesale price?      21 MR. FAUCI: Object to the form.      22 THE WITNESS: It is my understanding.</p>	<p style="text-align: right;">Page 32</p> <p>1 would be so kind as to take that out. I have      2 copies for you and counsel.      3 Okay. It looks like you have      4 successfully managed to get Abbott Exhibit 19. That      5 puts you ahead of others we have done before.      6 Abbott Exhibit 19 is a copy of the United      7 States' complaint against Abbott Labs in this case.      8 I take it, given your responses so far, you have      9 never seen this document. Would that be fair to      10 say?      11 A. Yes. That's correct.      12 Q. If I could ask you to go to page 10 of      13 the complaint, in particular, paragraph 31, there      14 is a listing of drugs and their corresponding NDC      15 numbers that are at issue in the case, that is at      16 the bottom of page 10, carrying over to page 11. Do      17 you see that?      18 A. Yes.      19 Q. And you are familiar with what a National      20 Drug Code is, correct?      21 A. Yes.      22 Q. If we look through the listing of the</p>
<p style="text-align: right;">Page 31</p> <p>1 BY MR. TORBORG      2 Q. How did you obtain that understanding?      3 A. I think I saw it on the document that you      4 sent.      5 Q. Okay. Do you have an understanding of      6 the nature of the damages that the United States is      7 seeking against Abbott?      8 A. I do not.      9 Q. And do you have an understanding of the      10 types of drug products that are at issue in the      11 case?      12 A. I do not.      13 Q. To your left, Ms. Terrebonne, are a      14 couple of boxes that have documents. I'm not going      15 to ask you about all of those. Those are copies of      16 exhibits that we have used with people who came      17 before you. From time to time, I would ask you to      18 take out Exhibit X. There are tabs in those orange      19 binders that indicate where you would find such      20 exhibits.      21 The first one I would like to go to, it      22 should be in the first volume at tab 19. If you</p>	<p style="text-align: right;">Page 33</p> <p>1 drugs, I think you will see that the drug products      2 fall into a few categories, including sodium      3 chloride injection, sodium chloride irrigation,      4 sterile water injection, sterile water irrigation,      5 vancomycin, then a number of dextrose solutions. Do      6 you see that?      7 A. Yes.      8 Q. Are you familiar with these drug      9 products?      10 A. Yes.      11 Q. Are you familiar with the term "large      12 volume parenterals"? Am I pronouncing that right?      13 A. Yes.      14 Large volume parenterals, no.      15 Q. How about parenterals?      16 A. I'm familiar with that.      17 Q. What are those?      18 A. Those are used IV.      19 Q. Have you come across, in your work, these      20 drugs?      21 A. Yes.      22 Q. And do you know how they are dispensed to</p>

<p style="text-align: right;">Page 34</p> <p>1 Medicaid beneficiaries?</p> <p>2 A. How they are dispensed? Through a</p> <p>3 pharmacy.</p> <p>4 Q. But these are not the type of -- these</p> <p>5 are not pills, correct?</p> <p>6 A. Correct.</p> <p>7 Q. They appear to be drugs that are supplied</p> <p>8 either through home IV or through some sort of</p> <p>9 infusion?</p> <p>10 A. Correct.</p> <p>11 Q. Do you have an understanding of the types</p> <p>12 of pharmacies in Louisiana who would have dispensed</p> <p>13 these drugs to Medicaid beneficiaries?</p> <p>14 A. Probably IV pharmacies.</p> <p>15 Q. Any other types?</p> <p>16 A. Well, it is not your normal retail</p> <p>17 pharmacy, so --</p> <p>18 Q. Would you agree that dispensing these</p> <p>19 types of drugs to Medicaid beneficiaries is a more</p> <p>20 cost-intensive procedure than pills?</p> <p>21 MR. FAUCI: Objection, form.</p> <p>22 THE WITNESS: I know there are -- it is</p>	<p style="text-align: right;">Page 36</p> <p>1 A. Nicholls State University and Northeast</p> <p>2 Louisiana University in Monroe.</p> <p>3 Q. And did you receive a degree from either</p> <p>4 of those institutions?</p> <p>5 A. From Northeast.</p> <p>6 Q. What was your degree in?</p> <p>7 A. Pharmacy.</p> <p>8 Q. I think I have seen somewhere that you</p> <p>9 are a registered pharmacist. Is that right?</p> <p>10 A. Correct.</p> <p>11 Q. What does it take to become a registered</p> <p>12 pharmacist in the State of Louisiana?</p> <p>13 A. You have to have your degree in pharmacy,</p> <p>14 and you have to pass your board and get your board</p> <p>15 -- your certificate renewed every year.</p> <p>16 Q. Are you still an active registered</p> <p>17 pharmacist?</p> <p>18 A. I am.</p> <p>19 Q. What types of continuing education</p> <p>20 courses does one have to take as a registered</p> <p>21 pharmacist in Louisiana, if any?</p> <p>22 A. You have to have 15 hours.</p>
<p style="text-align: right;">Page 35</p> <p>1 different than dispensing pills, I am aware of</p> <p>2 that.</p> <p>3 BY MR. TORBORG</p> <p>4 Q. How is it different?</p> <p>5 A. These pharmacies have IV hoods and they</p> <p>6 have certain packing that they have to adhere to,</p> <p>7 and the sterility and those kinds of things.</p> <p>8 Q. Is it your understanding that it</p> <p>9 typically costs more for pharmacies to dispense</p> <p>10 these drugs to Medicaid beneficiaries, than say, a</p> <p>11 pill?</p> <p>12 MR. FAUCI: Objection, form.</p> <p>13 THE WITNESS: I'm not familiar with the cost</p> <p>14 involved, I just know it is a different set of</p> <p>15 circumstances.</p> <p>16 BY MR. TORBORG</p> <p>17 Q. I would like to back up a little bit and</p> <p>18 walk through your educational background and work</p> <p>19 history briefly.</p> <p>20 Did you attend college?</p> <p>21 A. I did.</p> <p>22 Q. And where did you attend college?</p>	<p style="text-align: right;">Page 37</p> <p>1 Q. Have you taken any courses on the subject</p> <p>2 of -- the broad subject of payment rates for</p> <p>3 pharmacies?</p> <p>4 A. Not that I recall.</p> <p>5 Q. Have the courses focused more on the</p> <p>6 medical side of pharmacy?</p> <p>7 A. The clinical side.</p> <p>8 Q. Clinical side?</p> <p>9 A. (Witness nods head affirmatively.)</p> <p>10 Q. And do you have any advanced degrees?</p> <p>11 A. I do not.</p> <p>12 Q. What year did you graduate from</p> <p>13 Northeastern University? I'm sorry, Nicholls --</p> <p>14 give that one to me?</p> <p>15 A. Nicholls is the pre-pharmacy, and</p> <p>16 Northeast is where I received my pharmacy degree in</p> <p>17 1978.</p> <p>18 Q. That's called Northeast University?</p> <p>19 A. It is now called the University of</p> <p>20 Louisiana in Monroe.</p> <p>21 Q. UL Monroe?</p> <p>22 A. Uh-huh.</p>

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1 aware of other states who calculated their maximum 2 allowable cost in this fashion? 3 A. I am not. 4 Q. Do you recall discussing Louisiana's 5 method for establishing maximum allowable costs 6 with other states? 7 A. Not that I recall. 8 Q. Were you aware that the Louisiana method 9 for calculating maximum allowable cost limits was 10 similar to the way which Medicare calculated its 11 reimbursement for drugs using a median AWP? 12 MR. FAUCI: Object to the form. 13 THE WITNESS: I do not. 14 BY MR. TORBORG 15 Q. The last sentence of that paragraph that 16 I was referring to states, "LMAC limits may be 17 adjusted by Medicaid of Louisiana based on changes 18 in availability and EAC of the drugs." 19 Do you see that? 20 A. Yes. 21 Q. What is meant by "changes in availability 22 of drugs"?	1 A. An antibiotic. 2 Q. Do you believe there are issues with the 3 availability of vancomycin from some manufacturers? 4 A. Not that I recall. 5 Q. May have happened, you just don't recall? 6 A. Right. 7 Q. You can't recall any particular drugs for 8 which there was an availability issue. Is that 9 fair to say? 10 A. Not by name. I don't recall. My staff 11 may know, I may not know. 12 Q. Second paragraph under the LMAC section 13 of the state plan notes that an LMAC cost listing 14 would be distributed periodically and a provider 15 could get one at least annually? 16 A. Yes. 17 Q. What type of form would that document be 18 in? 19 A. It was a hard copy listing of the drugs 20 that were payable under our program, and we listed 21 the LMAC on the listing. 22 Q. And do you recall sending providers
Page 99	Page 101
1 A. Occasionally, providers would contact us 2 and say they were not able to purchase the drugs at 3 a price that would be reasonable for the LMAC 4 limit. So we would call the wholesaler and ask 5 them if it was available at that price, and they 6 would tell us yes or no, and we would adjust it 7 accordingly. 8 Q. Do you recall this happening where some 9 generic -- manufacturers of generic products, these 10 products would not be available, do you recall this 11 happening? 12 A. Right. 13 Q. Do you recall any specific drugs this 14 happened with? 15 A. I don't. 16 Q. Do you recall this issue ever arising 17 with the drug vancomycin? 18 A. Not to my knowledge. 19 Q. Do you know what kind of drug vancomycin 20 is? 21 A. I do. 22 Q. What is it?	1 copies of the LMAC? 2 A. Yes. 3 Q. Something they were particularly 4 concerned about, right, from -- 5 A. Yes. 6 Q. And what you were telling them in this 7 document from the State of Louisiana was we will 8 pay you this much in ingredient cost reimbursement 9 for these drugs, correct? 10 A. We didn't tell them we'd pay them, we 11 said these are the LMACs and the FULs for these 12 drugs. 13 Q. And you expected them to rely on that 14 information in deciding whether or not to 15 participate in the program, correct? 16 MR. FAUCI: Objection, form. 17 THE WITNESS: I don't know that they relied on 18 the drug prices listed on the information we sent 19 to them. I think they used it for information. 20 BY MR. TORBORG 21 Q. Information for what purpose? 22 A. For determining whether they needed to

<p style="text-align: right;">Page 170</p> <p>1 for generic drugs in the compendia, AWP prices, 2 were a reliable indication of how much providers 3 were paying for drugs, net of chargebacks, 4 discounts and rebates?</p> <p>5 MR. FAUCI: Objection, form.</p> <p>6 THE WITNESS: I didn't know that because I 7 didn't know what the chargebacks or the discounts 8 were.</p> <p>9 BY MR. TORBORG</p> <p>10 Q. Did you think, for example, that you 11 could just take off 20 percent from those prices 12 and get to a number that would be the acquisition 13 cost?</p> <p>14 MR. FAUCI: Objection, form.</p> <p>15 THE WITNESS: No.</p> <p>16 BY MR. TORBORG</p> <p>17 Q. And why is that?</p> <p>18 A. Because I didn't know what the actual 19 acquisition costs were.</p> <p>20 Q. Did you have reason to believe that you 21 could not just simply discount the AWP numbers by a 22 certain percentage, say, 20 percent, and get to a</p>	<p style="text-align: right;">Page 172</p> <p>1 all on whether you believed you could take a 2 discount, a set discount, say, of 20 percent and 3 get to a reliable actual acquisition cost for 4 multi-source drugs?</p> <p>5 MR. FAUCI: Objection, form.</p> <p>6 THE WITNESS: On the average.</p> <p>7 BY MR. TORBORG</p> <p>8 Q. Just for individual drugs?</p> <p>9 A. Well, what this is saying is the average 10 discount is that. For individual drugs, I know it 11 varies.</p> <p>12 Q. And did you know that varied -- there was 13 a wider variation for generic drugs?</p> <p>14 A. Yes.</p> <p>15 Q. And Myers and Stauffer wasn't telling you 16 anything in 1999 that you didn't already know about 17 that?</p> <p>18 MR. FAUCI: Objection, form.</p> <p>19 THE WITNESS: They documented it, yes.</p> <p>20 BY MR. TORBORG</p> <p>21 Q. But would you have known that before 22 1999?</p>
<p style="text-align: right;">Page 171</p> <p>1 reliable actual acquisition cost?</p> <p>2 MR. FAUCI: Objection, form.</p> <p>3 THE WITNESS: What I have been familiar with 4 is to conduct a survey so you would have that 5 document to represent what the average discount 6 was.</p> <p>7 BY MR. TORBORG</p> <p>8 Q. Why don't we take a look at Abbott 9 Exhibit 1051, one of the exhibits we marked here 10 today. It will be in that stack right in front of 11 you. It is the survey of dispensing costs, Myers 12 and Stauffer. There it is.</p> <p>13 In particular, I will direct your 14 attention to page 6. The last bullet before the 15 section "General" states, "The discounts from AWP 16 for multiple source drugs exhibited much greater 17 variation but averaged 32.6 percent for drugs 18 without full pricing and 69.6 percent for drugs 19 with full pricing."</p> <p>20 Do you see that?</p> <p>21 A. Yes.</p> <p>22 Q. Does that refresh your recollection at</p>	<p style="text-align: right;">Page 173</p> <p>1 MR. FAUCI: Objection, form.</p> <p>2 THE WITNESS: Based on reports that we had 3 received from the OIG and that kind of thing. I 4 did not conduct any surveys.</p> <p>5 BY MR. TORBORG</p> <p>6 Q. Going back to Abbott Exhibit 84, this is 7 the Florida report. The last page of the exhibit, 8 second page of Mr. Cook's response, he states at 9 the top of that page, first paragraph, "Injectable 10 products and associated intravenous fluids also 11 continue to be problematic. Manufacturers offer 12 contracts to most vendors providing very favorable 13 pricing, but manufacturers continue to market small 14 quantities of these through conventional sources 15 and report single unit pricing through the national 16 data sources. Any assistance your office might 17 offer in standardizing pricing in this market would 18 be beneficial."</p> <p>19 Do you see that?</p> <p>20 A. Yes.</p> <p>21 Q. Do you recall, Ms. Terrebonne, becoming 22 aware that the discounts on intravenous fluids and</p>

<p style="text-align: right;">Page 174</p> <p>1 injectable products tended to be large?</p> <p>2 MR. FAUCI: Objection, form.</p> <p>3 THE WITNESS: I do not recall.</p> <p>4 BY MR. TORBORG</p> <p>5 Q. Something you may have been aware of, but 6 you just don't recall as you sit here today?</p> <p>7 A. It is not something that distinctly I 8 would recall, no.</p> <p>9 Q. And do you have an understanding of what 10 Mr. Cook is saying when he notes that 11 "manufacturers continued to market small quantities 12 of these" -- and he is referring to injectable 13 products and associated intravenous fluids -- 14 "through conventional sources and report single 15 unit pricing for the national data sources."</p> <p>16 A. I do not.</p> <p>17 Q. Do you have an understanding of what 18 single unit pricing means?</p> <p>19 A. I do not. I would assume that is 20 something that is broken down on a single unit 21 rather than a bulk.</p> <p>22 Q. If I could ask you to go next to Abbott</p>	<p style="text-align: right;">Page 176</p> <p>1 change: States discount from the referenced 2 pharmaceutical pricing schedule shown as average 3 wholesale price vary by product class."</p> <p>4 Is that also something that you knew, Ms. 5 Terrebonne, that discounts from AWP could vary by 6 product class?</p> <p>7 A. I would think that, yeah, AWPs could vary 8 by product class.</p> <p>9 Q. Is that something you knew about from 10 1991 through 2001?</p> <p>11 A. In relation to this?</p> <p>12 Q. Just generally speaking.</p> <p>13 A. No. No. And I think our documents 14 supported that one of the items that they could not 15 purchase at the discount was immunosuppressant 16 drugs. So there is variation there.</p> <p>17 Q. And in this document, the author also 18 noted, "Generally, intravenous vehicles and 19 irrigation solutions are available at much greater 20 discounts than are other pharmaceuticals."</p> <p>21 Do you see that?</p> <p>22 A. Yes.</p>
<p style="text-align: right;">Page 175</p> <p>1 Exhibit 575. Ms. Terrebonne, this is a document 2 that was produced by Ven-A-Care from the Kansas 3 Medicaid program, I believe.</p> <p>4 If you will go to the last paragraph on 5 the first page, under "Final Policy," do you see 6 that?</p> <p>7 A. Yes.</p> <p>8 Q. They wrote: "Effective dates of service 9 1-1-95, all sterile irrigation solutions and all 10 large volume parenteral and small volume parenteral 11 fluid replacement vehicles for intravenous drug 12 administration which are billed as pharmacy claims 13 will be reimbursed at AWP less 50 percent (inhalation 14 solutions are not included in this reimbursement 15 change)."</p> <p>16 Do you see that?</p> <p>17 A. Yes.</p> <p>18 Q. Did you become aware that Kansas had at 19 some point changed or had a special reimbursement 20 methodology for large and small volume parenterals?</p> <p>21 A. No, I did not.</p> <p>22 Q. Go to the next page, "The rationale for</p>	<p style="text-align: right;">Page 177</p> <p>1 Q. Is that something you became aware of at 2 some point in time from 1991 through 2001?</p> <p>3 A. No.</p> <p>4 Q. Do you recall having discussions with 5 Ven-A-Care of the Florida Keys?</p> <p>6 A. I did not have any discussions with 7 Ven-A-Care.</p> <p>8 Q. Did you have any communications via a fax 9 or document with people from Ven-A-Care?</p> <p>10 A. I do not recall.</p> <p>11 Q. Does the name Zachary Bentley ring a 12 bell?</p> <p>13 A. No.</p> <p>14 (Exhibit Abbott 1054 was marked.)</p> <p>15 MR. TORBORG: For the record, what I have 16 marked as Abbott Exhibit 1054 bears Bates No. VAC 17 MDL 77742 through 63.</p> <p>18 BY MR. TORBORG</p> <p>19 Q. Ms. Terrebonne, for the record, these are 20 some more materials produced by Ven-A-Care of the 21 Florida Keys related to this case. In particular, 22 this was a collection of documents produced in a</p>

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1 file titled "Louisiana."

2 I would ask you to take a look at that if  
3 you would.

4 Ms. Terrebonne, do any of these pages  
5 look familiar to you?

6 A. I see my name on it, but I don't recall.

7 Q. Look at Bates page ending 77759. Do you  
8 see that?

9 A. Yes.

10 Q. This is a -- appears to be, at least, a  
11 fax from M. J. Terrebonne to Zachary Bentley at  
12 Ven-A-Care dated January 30 of 1998. Do you see  
13 that?

14 A. Yes.

15 Q. Is that your handwriting?

16 A. Yes.

17 Q. So it appears you had sent a fax to Mr.  
18 Bentley. Is that fair to say?

19 A. Yes.

20 Q. Does that refresh your recollection at  
21 all regarding communications that you had with  
22 Ven-A-Care?

1 Q. And then you wrote, "I would appreciate,"  
2 can you read that to me and into the record?

3 A. "If you could send me the information on  
4 the definition which exempts IV pharmacies from  
5 retail class of trade. Also, your findings of the  
6 states' analyses compared to the average  
7 acquisition price. Thanks."

8 Q. Do you recall why you were asking Mr.  
9 Bentley to provide information both on the  
10 definition of IV pharmacies and the findings of  
11 states' analyses?

12 A. I would only say we were probably looking  
13 at ingredient cost at that time.

14 Q. Does reading this refresh your  
15 recollection at all about conversations you may  
16 have had with Mr. Bentley or others at Ven-A-Care?

17 A. No.

18 Q. And it has been almost ten years since  
19 you actually -- more than ten years since you faxed  
20 this. Is that right?

21 A. Yes.

22 Q. So, it's fair to say there are a lot of

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1 A. No.

2 Q. If you look at the next page there, it  
3 appears to be next to the -- this appears to list  
4 NDCs and then reimbursement. Do you see that?

5 A. Yes.

6 Q. Do you recall providing Mr. Bentley with  
7 information regarding how much the State of  
8 Louisiana reimbursed for ingredients for a set of  
9 drugs?

10 A. I do not.

11 Q. If we go to the next page there, it  
12 appears to be part of the same fax. Is that right?

13 A. Yes.

14 Q. Is that your handwriting?

15 A. Yes.

16 Q. And did you write, "Zachary, Louisiana  
17 Medicaid reimburses the lower of 1, usual and  
18 customary charge, or 2, AWP minus 10.5 percent,  
19 plus a fee (the maximum fee is \$5.77). I have  
20 listed the AWP for the drugs," which you listed.  
21 Then you wrote -- is that what you wrote?

22 A. Yes.

1 communications you may have had with Ven-A-Care  
2 that you don't recall given the passage of time?

3 MR. FAUCI: Objection.

4 THE WITNESS: It is possible, yes.

5 BY MR. TORBORG

6 Q. And if we look at the charts that are on  
7 Bates pages 756 and 57, does it appear as though --  
8 you did not prepare this document, right, the  
9 charts?

10 A. I did not.

11 Q. Does it appear as though --

12 A. I don't think I did.

13 Q. Do you recall receiving these charts?

14 A. No, I don't.

15 Q. Do you have any reason to believe that  
16 you did not receive them?

17 A. I don't recall. I really don't.

18 Q. But if you did receive these, does it  
19 appear as though you are being advised of the  
20 differences for certain drugs between the brand  
21 name AWP and what Louisiana Medicaid was  
22 purportedly reimbursing?

<p style="text-align: right;">Page 234</p> <p>1 Q. Where should the profit be, in the 2 dispensing fee or the ingredient cost? 3 A. I think that is dependent on how you 4 structure your reimbursement methodology. 5 Q. It could come in, in your view, either 6 way and not violate any law? 7 MR. FAUCI: Objection. 8 THE WITNESS: Well, I think CMS charges you to 9 have a reasonable reimbursement, so whether you pay 10 low on the dispensing fee side and you put your 11 profits on the ingredient cost side, or vice versa, 12 they have a final say on approving that. 13 BY MR. TORBORG 14 Q. Has there been tension between Louisiana 15 and HCFA on where the profit should be, whether on 16 the ingredient side or the dispensing fee side? 17 MR. FAUCI: Objection. 18 THE WITNESS: No. 19 BY MR. TORBORG 20 Q. If I could ask you to take out Abbott 21 Exhibit 1051 again. It is this one here, the 1999 22 Myers and Stauffer report. In particular, I would</p>	<p style="text-align: right;">Page 236</p> <p>1 Do you see that? 2 A. Yes. 3 Q. And the drugs that are at issue in this 4 case that we saw in the complaint, those are 5 intravenous solutions, correct? 6 A. Yes. 7 Q. If we go to page, the next page, page 21 8 of the report, there is a chart that calculates the 9 unweighted mean total cost for pharmacies 10 dispensing IV prescriptions and then pharmacies not 11 dispensing IV prescriptions, right? 12 A. Correct. 13 Q. Cost being \$18.57 for the IV prescription 14 pharmacies, and \$5.55 for the pharmacies not 15 dispensing IV prescriptions. Do you see that? 16 A. Yes. 17 Q. Do you recall becoming aware of the fact 18 that pharmacies which dispensed IV prescriptions 19 had a higher cost to dispense? 20 A. I would say I was somewhat aware just 21 because their setting is different than the normal 22 retail setting.</p>
<p style="text-align: right;">Page 235</p> <p>1 like to direct your attention to page 5 of the 2 report, under "Summary of Findings." There is a 3 footnote 1 at the bottom of the page that states, 4 "The cost reported for pharmacies dispensing 5 intravenous prescriptions is not representative of 6 routine Medicaid prescription dispensing cost and 7 therefore is excluded from this media." 8 Do you see that? 9 A. Yes. 10 Q. If we go to page 20 of the 1999 Myers and 11 Stauffer report, on the ingredient cost and 12 dispensing fees, pages 20 and 21, do you see there 13 is additional discussion of the additional costs 14 involved in dispensing IV prescriptions? 15 A. Yes. 16 Q. On page 20, the report notes "The most 17 significant characteristic which affected pharmacy 18 dispensing costs was the provision of intravenous 19 solutions. Our analysis revealed significantly 20 higher cost of dispensing is associated with the 21 pharmacies in the sample that provided this 22 service."</p>	<p style="text-align: right;">Page 237</p> <p>1 Q. And this is something that Myers and 2 Stauffer advised you of in this, correct? 3 A. Correct. 4 Q. And then at the bottom of the page, there 5 is a footnote that says, "Although typical 6 dispensing fees reimburse less than dispensing cost 7 of IV pharmacies, they are generally able to break 8 even based on the margin allowed on ingredient cost 9 reimbursement." 10 Do you see that? 11 A. Yes. 12 Q. Do you understand what it is saying? 13 A. They are saying there is profit on the 14 ingredient side. 15 Q. Was that something that you were aware of 16 for the time period of 1991 through 2001, as the 17 pharmacy consultant and pharmacy director in 18 Louisiana Medicaid? 19 MR. FAUCI: Objection. 20 THE WITNESS: As stated in this document. 21 BY MR. TORBORG 22 Q. Well, did you become aware of the fact</p>

<p style="text-align: center;">Page 238</p> <p>1 that, in essence, the profit on the ingredient side 2 was subsidizing insufficient dispensing fees?</p> <p>3 MR. FAUCI: Objection.</p> <p>4 THE WITNESS: I would say no, I was not -- I 5 had an understanding of it, but I did not know it 6 until they documented it.</p> <p>7 BY MR. TORBORG</p> <p>8 Q. And Louisiana did not have a separate 9 dispensing or -- dispensing fee or compounding fee 10 for home IV providers. Is that right?</p> <p>11 A. Correct.</p> <p>12 Q. Some states did, correct?</p> <p>13 A. Yes.</p> <p>14 Q. Why didn't Louisiana?</p> <p>15 A. I would say the secretary at the time was 16 interested in formulating a discount in totality on 17 ingredient costs and dispensing fee across the 18 board.</p> <p>19 Q. Was consideration of the profit being 20 made on the ingredient side a factor in not 21 increasing or providing a separate fee for home IV 22 services?</p>	<p style="text-align: center;">Page 240</p> <p>1 for providing home IV drugs to Medicaid 2 beneficiaries, would the uncompensated higher cost 3 to dispense home IV prescriptions be something you 4 would look at?</p> <p>5 MR. FAUCI: Objection.</p> <p>6 THE WITNESS: I would say we paid it in 7 accordance with our state plan.</p> <p>8 BY MR. TORBORG</p> <p>9 Q. But if you were looking at the situation 10 today, as an informed observer who was there at the 11 time from 1991 to 2001, and you were asked to 12 determine how much Louisiana Medicaid overpaid, if 13 at all, providers for dispensing home IV solutions, 14 would you consider Myers and Stauffer's findings 15 that there was a much higher cost to dispense?</p> <p>16 MR. FAUCI: Objection.</p> <p>17 THE WITNESS: I would say we did not overpay. 18 We paid it in accordance with our state plan.</p> <p>19 BY MR. TORBORG</p> <p>20 Q. So, you would say any payment consistent 21 with the state plan is not an overpayment. Is that 22 right?</p>
<p style="text-align: center;">Page 239</p> <p>1 A. I don't know the answer to that.</p> <p>2 Q. Well, here you are told in this document 3 that Louisiana is not paying a dispensing fee that 4 is anywhere close to the cost of dispensing found 5 by Myers and Stauffer for home IV prescriptions. Is 6 that right?</p> <p>7 A. Yes.</p> <p>8 Q. So, fair to say that you were underpaying 9 those pharmacies?</p> <p>10 MR. FAUCI: Objection.</p> <p>11 THE WITNESS: Based on the report on the 12 dispensing side.</p> <p>13 BY MR. TORBORG</p> <p>14 Q. What do you mean by "on the dispensing 15 side"?</p> <p>16 A. On the dispensing cost side.</p> <p>17 Q. How about on the ingredient cost side?</p> <p>18 A. Well, based upon what is stated here, it 19 looks like they were getting a margin on the 20 ingredient cost side.</p> <p>21 Q. So, if someone wanted to determine how 22 much Louisiana Medicaid overpaid pharmacy providers</p>	<p style="text-align: center;">Page 241</p> <p>1 MR. FAUCI: Objection.</p> <p>2 THE WITNESS: I would say you have to look at 3 it, do a survey, conduct a survey and resubmit your 4 state plan.</p> <p>5 (Exhibit Abbott 1062 was marked.)</p> <p>6 MR. TORBORG: For the record, what I have 7 marked as Abbott 1062 is a series of e-mails, most 8 of which or all of which are copied to Ms. 9 Terrebonne and others, KYDMSPL-0111755 through 809.</p> <p>10 They were produced to us in connection 11 with another litigation. That's my understanding.</p> <p>12 BY MR. TORBORG</p> <p>13 Q. Ms. Terrebonne, were you on an e-mail 14 list that included other state pharmacy 15 administrators?</p> <p>16 A. Yes.</p> <p>17 Q. What was that called?</p> <p>18 A. What was the e-mail list called? I don't 19 know what it was called. Probably the National 20 Pharmacy Benefits Association -- the National 21 Pharmacy --</p> <p>22 Q. Not Medicaid Pharmacy Administrators, or</p>

<p style="text-align: right;">Page 242</p> <p>1 something like that?</p> <p>2 A. Yes.</p> <p>3 Q. When did you start on that e-mail</p> <p>4 distribution?</p> <p>5 A. Oh, it's been several years.</p> <p>6 Q. Do you still have those e-mails on your</p> <p>7 computer?</p> <p>8 A. I have some e-mails.</p> <p>9 Q. Now, this collection of documents was</p> <p>10 produced in sequential order. All appear to be</p> <p>11 different e-mails concerning reimbursement for</p> <p>12 compounding home IV-type issues of the type we were</p> <p>13 just talking about. I would like to ask you to go</p> <p>14 to the Bates page ending 768. Are you there?</p> <p>15 A. Yes.</p> <p>16 Q. The bottom of the page is an e-mail from</p> <p>17 Rachel Broussard. She was on your staff?</p> <p>18 A. Yes.</p> <p>19 Q. Is on your staff?</p> <p>20 A. (Witness nods head affirmatively.)</p> <p>21 Q. She e-mailed a distribution to the state</p> <p>22 Medicaid administrators; is that right?</p>	<p style="text-align: right;">Page 244</p> <p>1 did with the information it received?</p> <p>2 A. We haven't done anything yet.</p> <p>3 Q. Why is that?</p> <p>4 A. Probably because we have lots of other</p> <p>5 things to do, so it is still on our to-do list.</p> <p>6 Q. If reimbursement were cut on the</p> <p>7 ingredient side, the actual acquisition cost, is</p> <p>8 that something you think would go to the top of</p> <p>9 your list and re-create a separate fee for</p> <p>10 compounding?</p> <p>11 MR. FAUCI: Objection.</p> <p>12 THE WITNESS: I don't know, it's a kind of</p> <p>13 whatever-is-on-top-of-the-list sort of day here.</p> <p>14 BY MR. TORBORG</p> <p>15 Q. And what runs the agenda on what is at</p> <p>16 the top of the list?</p> <p>17 A. The secretary of the department.</p> <p>18 Q. And the secretary of the department gets</p> <p>19 calls from providers?</p> <p>20 A. Yes. Mostly we get calls from providers.</p> <p>21 Q. Do you recall getting phone calls from</p> <p>22 providers concerning the need for a compounding</p>
<p style="text-align: right;">Page 243</p> <p>1 A. Yes.</p> <p>2 Q. Do you recognize those names?</p> <p>3 A. Yes.</p> <p>4 Q. And she asked, "We are interested in</p> <p>5 information regarding policies in reimbursement of</p> <p>6 compound prescriptions. Are other states</p> <p>7 reimbursing pharmacy providers for compound</p> <p>8 prescriptions? If so, what is your policy for</p> <p>9 reimbursing compounds, what is your reimbursement</p> <p>10 methodology and do you reimburse a compound fee?"</p> <p>11 Do you see that?</p> <p>12 A. Yes.</p> <p>13 Q. Do you recall Ms. Broussard seeking</p> <p>14 information from other states concerning</p> <p>15 reimbursement of compound prescriptions?</p> <p>16 A. Yes.</p> <p>17 Q. What motivated that? Was it the Myers</p> <p>18 and Stauffer report?</p> <p>19 A. No. Occasionally, we will get calls on</p> <p>20 compounding scrips, and we don't have any policies</p> <p>21 so we were looking at other states' policies.</p> <p>22 Q. Do you know what, if anything, Louisiana</p>	<p style="text-align: right;">Page 245</p> <p>1 fee?</p> <p>2 A. We have gotten a few calls, yes.</p> <p>3 Q. Do you recall what you have told them</p> <p>4 about why it is Louisiana is not paying one?</p> <p>5 A. Rachel answers those calls primarily. We</p> <p>6 try to work with the pharmacist to, under our</p> <p>7 existing policy, to go ahead and provide those</p> <p>8 drugs.</p> <p>9 Q. Well, how about the payment of a separate</p> <p>10 higher dispensing fee for compound prescriptions?</p> <p>11 A. That has not been addressed.</p> <p>12 Q. Okay. If I could ask you to get out</p> <p>13 Abbott Exhibit 292, which is one of the -- should</p> <p>14 be on the top right underneath the stack there. I</p> <p>15 think I put it in order. This is a document titled</p> <p>16 "Medicaid Pharmacy Bulletin," dated</p> <p>17 January/February 1997, titled "Medicaid</p> <p>18 Reimbursement for the Pharmacy Component of Home IV</p> <p>19 Therapy."</p> <p>20 Do you see that?</p> <p>21 A. Yes.</p> <p>22 Q. And you recall getting these bulletins.</p>

<p style="text-align: right;">Page 246</p> <p>1 Is that right?</p> <p>2 A. Yes.</p> <p>3 Q. And you were at some point a member of</p> <p>4 the editorial staff. Is that right?</p> <p>5 A. Yes. For a short tenure.</p> <p>6 Q. And did you retain copies of these</p> <p>7 bulletins?</p> <p>8 A. I don't believe I have them anymore.</p> <p>9 Q. If I wanted to get my hands on these,</p> <p>10 what is the best way to get them, other than the</p> <p>11 ones I have? If I wanted to get all of the copies</p> <p>12 of these, what is your -- do you have any guidance</p> <p>13 for me about how I might do that?</p> <p>14 A. I do not, other than you would get a</p> <p>15 pharmacy director that retained them all.</p> <p>16 Q. Was it your understanding that this was a</p> <p>17 publication that was widely recognized in the state</p> <p>18 Medicaid pharmacy administrator universe?</p> <p>19 A. Yes.</p> <p>20 Q. And do you recall when you were on the</p> <p>21 advisory panel of this publication, that there were</p> <p>22 annual meetings that were associated with this</p>	<p style="text-align: right;">Page 248</p> <p>1 the notion that dispensing home IV medications is</p> <p>2 more complex than dispensing of other outpatient</p> <p>3 drugs?</p> <p>4 A. I agree it is more complex.</p> <p>5 Q. Let me ask you to go to the next page. We</p> <p>6 are on page 390. It says, "Providers and</p> <p>7 pharmacist consultants concur that it is not</p> <p>8 appropriate to apply the same ingredient-based</p> <p>9 pricing mechanisms to home IV medications as those</p> <p>10 that apply to other outpatient drugs."</p> <p>11 Do you see that?</p> <p>12 A. Yes.</p> <p>13 Q. Did you agree with that?</p> <p>14 A. I don't know that I agree with it. I</p> <p>15 would say you would have to survey to determine</p> <p>16 what is the appropriate structure of the pricing</p> <p>17 mechanism that you utilize for home IV, although it</p> <p>18 should probably be different than normal retail</p> <p>19 business.</p> <p>20 Q. And if we go to the second paragraph</p> <p>21 under that section, it states, "Home IV treatments</p> <p>22 are frequently a combination of multiple drug</p>
<p style="text-align: right;">Page 247</p> <p>1 publication?</p> <p>2 A. I do not recall.</p> <p>3 Q. I would like to ask you to go to the</p> <p>4 second page of Abbott Exhibit 92, under the Section</p> <p>5 1, "The Development of Pricing Mechanisms for Home</p> <p>6 IV Medications," it states, "The establishment of a</p> <p>7 fair and reasonable pricing methodology for home IV</p> <p>8 products is a major concern of most state Medicaid</p> <p>9 programs. One of the major obstacles to the</p> <p>10 development of adequate home IV pricing</p> <p>11 methodologies is the fact that the dispensing of</p> <p>12 home IV medications is more complex than the</p> <p>13 dispensing of other outpatient drugs."</p> <p>14 Do you see that?</p> <p>15 A. Yes.</p> <p>16 Q. And was that something that you were</p> <p>17 aware of throughout the time 1991 through 2001?</p> <p>18 A. I do not recall.</p> <p>19 Q. Do you recall when you started receiving</p> <p>20 these bulletins?</p> <p>21 A. I do not.</p> <p>22 Q. Do you have any basis to disagree with</p>	<p style="text-align: right;">Page 249</p> <p>1 entities dispensed in varying doses and dispensed</p> <p>2 several times daily. Although it may be minimal to</p> <p>3 moderate in quantity over an entire treatment,</p> <p>4 large volumes of medications are generally</p> <p>5 administered. It is therefore difficult to</p> <p>6 estimate based on a single daily or even weekly</p> <p>7 administration the purchase price these providers</p> <p>8 are paying with volume and trade discounts. These</p> <p>9 discounts are generally not revealed in drug</p> <p>10 publications such as Red Book, Blue Book, and</p> <p>11 DataBank. Consequently, programs are reluctant to</p> <p>12 increase reimbursement for home IV medications,</p> <p>13 suspecting that reported costs for these substances</p> <p>14 may already be exaggerated."</p> <p>15 Do you see that?</p> <p>16 A. Yes.</p> <p>17 Q. Do you have an understanding of what that</p> <p>18 last sentence is saying?</p> <p>19 A. What I think it is saying is that the</p> <p>20 programs -- and that would be the Medicaid programs</p> <p>21 -- are reluctant to increase the reimbursement for</p> <p>22 home IV based upon the increase in cost of the</p>

<p style="text-align: right;">Page 250</p> <p>1 ingredients for those substances.</p> <p>2 Q. Was that consistent with the experience</p> <p>3 in Louisiana?</p> <p>4 MR. FAUCI: Objection.</p> <p>5 THE WITNESS: I do not recall that.</p> <p>6 BY MR. TORBORG</p> <p>7 Q. May have been, but you don't recall?</p> <p>8 A. I wouldn't know without doing an</p> <p>9 analysis, which I did not do.</p> <p>10 Q. Are you familiar, Ms. Terrebonne, with</p> <p>11 something called findings and assurances under the</p> <p>12 federal regulations for reimbursement of</p> <p>13 prescription drugs, under the federal regulations?</p> <p>14 A. There are assurances. I believe you</p> <p>15 submit a letter to CMS assuring that you will</p> <p>16 adhere to your state plan.</p> <p>17 Q. If I could ask you to go to Abbott</p> <p>18 Exhibit 284 in that same binder there. This is a</p> <p>19 copy of a federal regulation. In particular, I</p> <p>20 would like to ask you to go to the last page of the</p> <p>21 exhibit. The second column, "447.333, State Plan</p> <p>22 Requirements, Findings and Assurances." Do you see</p>	<p style="text-align: right;">Page 252</p> <p>1 A. I would answer that saying yes, I have</p> <p>2 seen that within that time period.</p> <p>3 Q. At some point in that time period, did</p> <p>4 that quit happening?</p> <p>5 MR. FAUCI: Objection.</p> <p>6 THE WITNESS: I don't know. I don't know.</p> <p>7 BY MR. TORBORG</p> <p>8 Q. Well, are you doing them today?</p> <p>9 A. I am not doing them today.</p> <p>10 Q. Do you know of anyone who is?</p> <p>11 A. I don't know.</p> <p>12 Q. Who would know whether or not Louisiana</p> <p>13 is doing that today, providing those findings and</p> <p>14 assurances called for by the statute?</p> <p>15 A. Probably someone in our policy section.</p> <p>16 Q. If I could ask you to go to Abbott</p> <p>17 Exhibit 137. This is a letter dated February 16,</p> <p>18 2000, from the office of Attorney General, Medicaid</p> <p>19 Fraud Control Unit, State of New York, from Patrick</p> <p>20 Lupinetti. Also at the top are Elliott Spitzer and</p> <p>21 Jose' Maldonado. This is to a pharmacy director in</p> <p>22 Cheyenne, Wyoming. Take a look at that document,</p>
<p style="text-align: right;">Page 251</p> <p>1 that?</p> <p>2 A. Yes.</p> <p>3 Q. Under "B, Findings and Assurances," it</p> <p>4 states, "Upon proposing a significant state plan</p> <p>5 change in payments for prescription drugs and at</p> <p>6 least annually for multiple source drugs and</p> <p>7 triannually for all other drugs, the agency must</p> <p>8 make the following findings and assurances."</p> <p>9 And it lists that and goes on. Are you</p> <p>10 familiar with this regulation?</p> <p>11 A. Somewhat. I haven't seen it in a while.</p> <p>12 Q. Do you know if Louisiana, when was the</p> <p>13 last time Louisiana provided the annual findings</p> <p>14 and assurances for multiple source drugs?</p> <p>15 A. I do not.</p> <p>16 Q. Is it something that you think you would</p> <p>17 be familiar with if it was done?</p> <p>18 A. The policy section, our policy section</p> <p>19 would submit that to CMS.</p> <p>20 Q. Do you recall Louisiana, in the period</p> <p>21 1991 to 2001, providing the findings and assurances</p> <p>22 called for in 477.333?</p>	<p style="text-align: right;">Page 253</p> <p>1 Ms. Terrebonne, and let me know if you are familiar</p> <p>2 with this type of document.</p> <p>3 Ms. Terrebonne, do you recall this type</p> <p>4 of document?</p> <p>5 A. I recall some of the names but I don't</p> <p>6 recall the document.</p> <p>7 Q. Which names do you recall?</p> <p>8 A. Mary Reardon, Caroline McElroy.</p> <p>9 Q. Do you recall those individuals making a</p> <p>10 presentation at a national conference of state</p> <p>11 Medicaid personnel about this topic of using</p> <p>12 revised average wholesale prices?</p> <p>13 A. I don't recall.</p> <p>14 Q. Do you recall that an effort was made in</p> <p>15 1999, 2000 and 2001 time frame where the Department</p> <p>16 of Justice spearheaded an effort to get new</p> <p>17 information on certain injection, intravenous and</p> <p>18 inhalation drugs?</p> <p>19 A. I know they were involved in something to</p> <p>20 do with that, yes. I recall reading it.</p> <p>21 (Exhibit Abbott 1067 was marked.)</p> <p>22 MR. TORBORG: For the record, what I have</p>